Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report

Durable Medical Equipment (DME) and Accessories; Orthotics and Prosthetics (O & P); Supplies and Other

Wednesday, June 2, 2016

Introduction and Overview

Approximately 60 people attended. The agenda included 12 items.

Cindy Hake, Chair, of the CMS' HCPCS Coding Workgroup, provided an overview of the HCPCS public meeting procedures as it relates to the overall HCPCS coding process.

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

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

Information provided at the CMS HCPCS Public Meetings is considered by the CMS HCPCS Coding Workgroup at a subsequent workgroup meeting. The Workgroup reconvenes after the public meetings and reconsiders its preliminary coding recommendation in light of any new information provided, and formulates its final coding decisions. CMS maintains the permanent HCPCS Level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare

insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

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

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

HCPCS Public Meeting Agenda Item # 1

Wednesday, June 2, 2016

Application# 16.082

TOPIC

Request to establish a new Level II HCPCS add-on code to identify a custom-fabricated flexible inner socket, Trade Name: Environmentally Managed Systems (EMS) Socket.

Applicant's suggested language: "L5XXX, Addition to Lower Extremity, Below Knee custom fabricated, enhanced static co-efficient of friction, Multi-Surface Socket System – EMS".

BACKGROUND

Environmentally Managed Systems (EMS) submitted a request to establish a new Level II HCPCS code to specifically identify the EMS Socket. According to the applicant, the EMS Socket is a custom-fabricated, injection molded, urethane, flexible, inner-socket with multi-surface interface that increases the surface contact area 100%, and that increases the coefficient of friction between the liner and socket 400% for increased suspension and control. The flexible supracondylar area of the inner socket conforms to the limb under vacuum, giving stability without rigidity. This allows for low rigid trim lines to reduce stress on the sleeve while not restricting range of motion. The unique flexible distal end with "air cushion" allows for some distal movement between the EMS flexible inner socket and definitive outer socket frame, while maintaining total contact and minimizing distal pressure to the limb during weight bearing.

The EMS is recommended for use with a vacuum volume management system with vacuum pump with a rigid external frame socket and urethane gel liner between the limb and socket. The system can be used for below-knee or above-knee prosthetic applications. The EMS is custom-fabricated, based on a negative limb cast provided by the practitioner. The multi-surface flexible socket is created using a proprietary molding technique and supplied back to the practitioner for patient fitting and definitive socket fabrication. The EMS socket's advantages are applicable for amputees in mobility classes K2-K4.

The applicant comments that a new code is warranted because there is no existing HCPCS add-on code that describes the patented, dynamically-activated, multi-surface, flexible, inner-socket design.

PRELIMINARY HCPCS CODING RECOMMENDATION

One of the following existing codes, based on the level of amputation, adequately describes the EMS socket:

L5645, ADDITION TO LOWER EXTREMITY, BELOW KNEE, FLEXIBLE INNER SOCKET, EXTERNAL FRAME

L5651, ADDITION TO LOWER EXTREMITY, ABOVE KNEE, FLEXIBLE INNER SOCKET, EXTERNAL FRAME

L5653, ADDITION TO LOWER EXTREMITY, KNEE DISARTICULATION, EXPANDABLE WALL SOCKET

The use of existing code L5999 "Lower extremity prosthesis, not otherwise specified" is inappropriate to identify the EMS socket.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. For codes, L5645, L5651, and L5653, Pricing = 38.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision, stating that the L-codes that were part of CMS' preliminary coding recommendation "do not have the same function as the EMS Socket system." There are several key features that are unique to the EMS inner socket, which improve limb health, spatial awareness, and control of the prosthetic leg. Specifically, the EMS is not a volume or pressure-based socket. The EMS increases the linkage between the limb and the socket by over 400%, as compared with "standard" sockets. And the EMS increases surface area by 100%, as compared with "standard" sockets. The EMS socket is a custom-manufactured system, which allows for varying the relationship with forces required to stabilize the residual limb within the socket. The speaker reiterated the original request for a unique code to describe the EMS socket.

HCPCS Public Meeting Agenda Item # 2

Wednesday, June 2, 2016

Application# 16.083

TOPIC

Repeat request to establish a new Level II HCPCS code to identify a semi-rigid and malleable lower limb device, and to consider the device an orthotic, Trade Name: Tibial Ankle Foot Orthoses (TAFO).

BACKGROUND

PFS Med, Inc. submitted a request to establish a new code to identify the Tibial Ankle Foot Orthoses (TAFO). According to the applicant, the TAFO is a prefabricated, semi-rigid, malleable, ankle foot “orthosis” with replaceable components for long-term usage through the entire span of trauma. The TAFO provides support and stabilization while restricting or eliminating motion in the injured ankle/heel complex and/or tibia/fibula area. The TAFO is indicated for a wide range of trauma or complex lower extremity injuries. The TAFO is typically worn at all times, except for skin checks, dressing changes, or range of motion exercises.

The TAFO is issued either while the patient is an inpatient, or when they are an outpatient in a freestanding facility. The TAFO is designed to be “customized” by a qualified practitioner, taking into account patient size, dressings, ankle positioning, skin integrity, tone, and external fixator placement. The practitioner will also educate the patient and family on the donning/doffing and the wear schedule.

The applicant comments that no existing code category describes the TAFO because it is unique and different from other devices that may be used for traumatic injuries.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the TAFO has not been approved. Existing code L4398 "Foot drop splint, recumbent positioning device, prefabricated, off-the-shelf" adequately describes the product of this request.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision, stating that the TAFO is improperly categorized as an off-the-shelf recumbent positioning device. The company has made

changes to the device, addressing safe mobility by adding a skid-resistant foot plate. The TAFO stabilizes the foot and ankle during touch-down weight-bearing during ambulation with a crutch or walker, and "is used for ambulatory patients". "The TAFO is conducive to healing of significant trauma injuries to the lower leg." The speaker commented that "fitting" is a critical component of the TAFO. It is a "niche splint for complex lower extremity trauma," and, as such, it is a fracture orthosis. Additionally, the company has redesigned their website with fitting and customization sections that are exclusively for practitioners and therapists.

HCPCS Public Meeting Agenda Item # 3

Wednesday, June 2, 2016

Application# 16.085

TOPIC

Request to establish a new add-on code to identify an electronic device with its own separate microprocessor unit, which feeds motion and relational data to the main processor of the C-Leg 4, which enable control for the "intuitive stance function and backwards walking", Trade Name: the Inertial Motion Unit (IMU).

Applicant's suggested language: "L5XXX – Addition to endoskeletal knee-shin system, Inertial Motion Unit (IMU) control for intuitive stance function and backwards walking".

BACKGROUND

Otto Bock HealthCare submitted a request to establish a new code to identify a separate hardware component of a microprocessor knee joint, the Inertial Motion Unit (IMU). According to the applicant, the IMU is a separate hardware component added to the newest version of the C-Leg, the C-Leg 4. The C-Leg 4 is a microprocessor-controlled prosthetic knee component used on a lower limb prosthesis. The IMU component allows the knee to perform a different function than traditional microprocessor knees, including earlier versions of the C-Leg. It allows the amputee to intuitively stand while loading the prosthetic limb to bear all of the body weight without collapsing of the knee joint. It also provides stability when taking steps backwards.

The IMU component is a complex electronic hardware device with its own microprocessor (separate from the main microprocessor) that processes information related to the movement, direction, and velocity of the prosthesis in space, using data obtained from a triad of accelerometers and triad of gyroscopes. This processed information is fed into the main microprocessor of the knee. The C-Leg 4 is useful to a person with a lower-limb amputation or congenital defect, at Levels through the knee, femur, hip, or pelvis. By replacing the function of an amputated or missing knee, the device serves the medical purpose of improving the functioning of a malformed body member.

The applicant comments that a new code is warranted because existing microprocessor-control code categories do not describe the IMU. A unique HCPCS code for the IMU will: facilitate access to this new technology; enable payers to capture important product-specific data about this feature/functionality; and facilitate smoother claims processing with a specific code to describe this feature/functionality, as compared to use of a miscellaneous code.

PRELIMINARY HCPCS CODING RECOMMENDATION

The following existing codes only, and together, adequately describe all components of C-Leg devices.

L5828, ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING AND STANCE PHASE CONTROL

L5845, ADDITION, ENDOSKELETAL, KNEE-SHIN SYSTEM, STANCE FLEXION FEATURE, ADJUSTABLE

L5848, ADDITION, TO ENDOSKELETAL KNEE-SHIN SYSTEM, FLUID STANCE EXTENSION, DAMPENING FEATURE, WITH OR WITHOUT ADJUSTABILITY

L5856, ADDITION, TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, SWING AND STANCE PHASE, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE

L5920, ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE OR HIP DISARTICULATION, ALIGNABLE SYSTEM

L5930, ADDITION, ENDOSKELETAL SYSTEM, HIGH ACTIVITY KNEE CONTROL FRAME

L5950, ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE, ULTRA-LIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL)

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing codes apply to this product if covered. For codes L5828, L5845, L5848, L5856, L5920, L5930, and L5950, Pricing = 38.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision, stating that "the continued development of microprocessor knee joints has provided amputees the benefit of additional function, reduction in falls, and improvements in stability compared to mechanical knee joints." Furthermore, improvements in the C-Leg 4 functionality, such as the intuitive stance and backwards walking, are due to hardware additions, not software enhancements. Such hardware improvements are not captured in existing codes. Internal Motion Unit technology was not available when the code L5856 was established. "Without additional coding, such investments may cease to exist."

HCPCS Public Meeting Agenda Item # 3

Wednesday, June 2, 2016

Application# 16.086

TOPIC

Request to establish a new Level II HCPCS code to identify a device that controls inversion/eversion of the foot, Trade name: Agilium Freestep Osteoarthritis Device Solution.

Applicant's suggested language: LXXXX, "Ankle foot orthosis, single upright with ankle joint, control of the subtalar joint to redirect ground reaction force to reduce knee varus/valgus moment, prefabricated includes fitting and adjustment".

BACKGROUND

Otto Bock HealthCare submitted a request to establish a new code to identify the Agilium. According to the applicant, the Agilium is an ankle foot orthosis, consisting of four main components: the trimable footplate, free range ankle joint, varus/valgus adjustable uprights, and a tibial strap and pad configuration.

The Agilium "locks" the subtalar joint to control eversion/inversion of the foot and applies counterforce to the fibular/tibial head, the combination of which "offloads the medial/lateral knee compartment". This is measured by the shift in the weight-bearing line to an area of healthy cartilage. The Agilium is indicated for medial/lateral unicompartmental knee osteoarthritis without knee instability. It is intended as an alternative to existing knee orthoses for some patients, and as an alternative to total knee replacement surgery for some patients.

The applicant comments that a new HCPCS code is warranted to identify the Agilium because it performs a significantly different function than items categorized under existing AFO HCPCS codes, which are indicated for foot and ankle instability. The Agilium is also different in that it utilizes ground reaction force, via a lever arm, in the frontal plane to counteract the varus/valgus adduction moment.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish AXXXX "Inversion/eversion correction device".

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision to establish a new "A" code for the Agilium Freestep. The speaker commented that "the HCPCS workgroup has determined that the product does not fit in the brace benefit category," because "A-codes usually describe disposables that do not require professional adjustments". The Agilium "meets the criteria to be considered a brace" because it "clearly supports a deformed body member," and because it requires the clinician to make fitting adjustments. Therefore, it is justified to consider the Agilium an ankle-foot orthosis and to establish an L-code for it, rather than an "A" code.

HCPCS Public Meeting Agenda Item # 4

Wednesday, June 2, 2016

Application# 16.087

TOPIC

Request to EITHER establish a new code to identify the Very Good Knee (VGK), OR revise existing code L5856 which currently reads, "Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type", to instead read, "Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor or vortex with motion control feature, auto-adaptive resistance, adjustable stumble recovery, swing and stance phase, includes electronic sensor(s), any type".

BACKGROUND

On behalf of Orthomolitity, a request was submitted to EITHER create a new code to identify the Very Good Knee (VGK), OR revise existing code L5856 which currently reads, "Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type", to instead read, "Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor or vortex with motion control feature, auto-adaptive resistance, adjustable stumble recovery, swing and stance phase, includes electronic sensor(s), any type".

According to the applicant, the proposed revision would capture the VGK, which is similar to other microprocessor-controlled knee (MPK) knee-shin systems coded at L5856 except the MPK constantly adjusts the hydraulic resistance in the knee. The MPK makes the adjustments by sensing the forces applied to the foot and knee. The constant timing of the hydraulic resistance is referred to as being intelligent. The VGK is a prosthetic knee joint that fits the L5856 code in all ways, but it uses Vortex with motion control mechanism, rather than microprocessor, to achieve the same intelligence. The VGK was developed with the goal of improving stability and simplifying the use of a prosthetic knee while providing the same intelligence as a microprocessor-controlled knee.

The VGK is an external prosthetic knee joint, designed to give above knee, knee disarticulation, and hip articulation amputees an intuitive and instinctive sense of control. The VGK is unique in that its primary design is to reduce the fear of falling, give a safe stable support and to reduce fall risk from a stumble with advanced stumble recovery technology. The VGK has a hydraulic piston and cylinder. The VGK uses a new method of auto adjusting intelligence, incorporating Vortex Metering System (VMS) and Motion Feedback System (MFS), at all phases of gait cycle.

The VGK is indicated for persons with above knee, knee disarticulation, and hip disarticulation amputations and K2-K4 activity level. The main goal of the VGK is to provide a safety system within the knee to respond to the patient's use.

The applicant comments that a new or revised code is needed because existing codes do not describe the VGK.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify this product has not been approved. Existing code L5828 "Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control" adequately describes the VGK.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision, because the VGK offers capabilities not included in knee additions coded at L5828. Specifically, the VGK offers auto-compensation; dual parameter swing and stance; 70 degrees of yielding stance support; locked in stance with No Fall risk; increased side-stepping ability; stumble-free recovery in free swing; backwards walking; and weight-compensating control for 35 pounds. The VGK is a microprocessor knee with additional features. The applicant reiterated the original request to revise the existing code L5856 to describe the Vortex Metering System, auto-adaptive resistance and adjustable stumble recovery. Alternatively, the speaker requested a new code to describe the unique functions of the VGK.

HCPCS Public Meeting Agenda Item # 5

Wednesday, June 2, 2016

Application# 16.088

TOPIC

Request to establish two new Level II HCPCS codes to identify an alarm designed for mounting on a walker, Trade Name: Walker Alarm. One code to identify an alarm with a battery charger, another code to identify an alarm without a battery charger.

BACKGROUND

Walker Aid, LLC submitted a request to establish two new codes to identify the Walker Alarm: one code for an alarm with a battery charger, and one code for an alarm without a battery charger. According to the applicant, the Walker Alarm attaches to a standard walker. It performs echo measurements and indicates when objects are within 15 inches of the walker, and also when the user is more than 15 inches away from the walker. A green light glows when there are no objects (obstacles) close to the walker and when the user is safely near the walker. The green glow is designed to be an easy-to-monitor, positive stimulus. When the walker is in an unsafe position relative to the user, and the potential for a fall exists, the alarm will flash red and blue lights, emit a duck call sound, and vibrate. This serves as a “feedback mechanism” for the user to return to a safe position near to the walker. It also provides an alarm audible by caregivers.

The Walker Alarm is designed to safely assist a person in learning to use a Walker and to provide feedback to promote safe ongoing use. The medical purpose is to allow patients in any setting to ambulate in a safer environment.

The applicant comments that a new code is warranted because the product is not listed among existing HCPCS codes.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A9280 "ALERT OR ALARM DEVICE, NOT OTHERWISE CLASSIFIED" adequately describes alarm devices, and is available for assignment by insurers to identify the Walker Alarm.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

Pricing = 00

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker stated that existing code A9280 "is nebulous because it does not say where the alarm is used, and because this is a new product". The speaker described how the Walker Alarm operates as well as the benefits of using it for the visual and hearing impaired. The speaker claimed that use of the Walker Alarm will reduce hospital visits, and "the major benefit for Medicare will be to reduce the chance of a $30,000 cost from a broken bone." The speaker asked that CMS consider this product to be DME or an accessory to DME.

HCPCS Public Meeting Agenda Item # 6

Wednesday, June 2, 2016

Application# 16.089

TOPIC

Repeat request to establish a new HCPCS Level II code to identify a knee rehabilitation machine, Trade Name: X10 Pressure Modulated Knee Rehabilitation (PMKR) system.

BACKGROUND

Halley Orthopedics submitted a request to establish a new code to identify the X10 Pressure Modulated Knee Rehabilitation (PMKR) system. According to the applicant, the PMKR machine is a powered, computer-controlled exercise machine, which consists of a chair with on leg rest/ foot pedal and cushioned ankle grips. The chair assembly is connected to an onboard computer with LED touchscreen that stores a selection of treatment programs. The patient sits in the chair and positions their leg, selects one of the treatment programs, and commences a "patient directed" physical therapy program, including active and passive range of motion, quadriceps and hamstring stretching and strengthening, and neuromuscular reeducation. The computer collects and stores data during each session for transmission to cloud-based storage for review by the patient's medical team to determine compliance, strength and range of motion, and as a basis for decisions about future therapy.

PMKR machines represent a revolutionary change to post-operative rehabilitation from knee surgery by introducing a modular, portable, patient-centric, integrated telemedicine system that simultaneously improves the quality of patient outcomes, reduces cost, and provides an objective registry of daily patient data that can be used to generate further value. The machines eliminate reliance on 1:1 skilled physical therapists, replacing it with more efficient telemedicine.

PMKR machines are rented to patients for use in recovering from knee surgery or injury.

The applicant comments that existing code E0935 for continuous passive motion devices, as previously assigned to the X10 PMKR, does not adequately describe the X10 device. A new code is warranted because "the mechanisms' components, applications and uses of PMKR machines are completely different from CPM machines".

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code E0935 "Continuous passive motion exercise device for use on knee only" adequately describes the device that is the subject of this request. This code category takes into account all types of CPM machines.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code apply to this product if covered. Pricing = 31.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item # 7
Wednesday, June 2, 2016

Application# 16.090

TOPIC

Request to establish a new Level II HCPCS code to identify a convertible mask platform that converts between a full face mask interface and a nasal cushion mask interface, Trade Name: Philips Respironics Wisp Full Face Convertible Mask.

Applicant's suggested language: Convertible interface used with positive airway pressure device.

BACKGROUND

Phillips Respironics submitted a request to establish a new code to identify the Philips Respironics Wisp Full Face Convertible Mask. According to the applicant, the hallmark of the Philips Respironics Wisp Full Face Mask is its ability to switch between different types of interfaces without replacing the entire product. The core components are the following: frame; quick release elbow tubing (12 inches in length); and headgear. The product is used to enable air to flow effectively and safely from a PAP device or RAD to the patient. "The patient may simply switch cushions to go from a full face mask to a nasal mask as the need arises for reasons such as skin breakdown, etc…, thereby contributing to increased patient compliance" with CPAP device or RAD/bi-Level therapies. The WISP is indicated for patients with obstructive sleep apnea or other serious respiratory disorders.

The applicant comments that existing codes A7030 "Full face mask used with positive airway pressure device, each" and A7034 "Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap" do not accommodate a single device that is both a full face mask and a nasal mask. Therefore, a new code is warranted, and the new code could be used in conjunction with the existing codes for replacement cushions, or, alternatively, additional new codes could be established for replacement cushions used with this interface.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify "convertible interface used with positive airway pressure device" has not been approved. The "convertible interface used with positive airway pressure device" is already included in the existing code A7034 "Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap". As such, it is not separately billable. Separate billing using any other code could be considered unbundling and duplicative.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker reiterated the original request to establish a new HCPCS code to identify the device, stating that "the flexibility of the convertible mask may promote patient compliance," and the efficacy of PAP treatment depends on patient compliance. However, coding barriers exist for patients to get the product. "There is currently no existing code that would clearly and unambiguously apply to a convertible mask. Major coding and administrative issues will arise if the preliminary decision to assign the convertible mask to HCPCS code A7034 is finalized." A new code "would promote patient compliance," "avoid confusion and ambiguity in coding," and "has the potential to generate material and financial efficiencies in the Medicare program".

HCPCS Public Meeting Agenda Item # 8

Wednesday, June 2, 2016

Application# 16.091

TOPIC

Sixth request to code the SwallowSTRONG, a device used in oropharyngeal strengthening therapy. The 2016 -2017 request is to establish two new Level II HCPCS codes, one each to identify the two components of the SwallowSTRONG System: the SwallowSTRONG Device, and the Pressure Transducer; and also to consider the devices Durable Medical Equipment.

Applicant's suggested language:

EXXX1 – Swallowing rehabilitation system

EXXX2 – Pressure transducer for swallowing rehabilitation system

BACKGROUND

Swallow Solutions, LLC submitted a request to establish two new codes to identify components of the SwallowSTRONG System: one to identify the SwallowSTRONG device, and one to identify the pressure transducer accessory. According to the applicant, the SwallowSTRONG System delivers oropharyngeal strengthening therapy, which is clinically proven as an effective treatment for dysphagia (swallowing disorders). The SwallowSTRONG System has two components. The first component, the SwallowSTRONG Device, "is a DME device", comprising a microprocessor, touch-screen user interface, electronics module, and embedded software. It directs the patient through therapy, but does not monitor any real-time physiological data (i.e., it is not a monitoring device). The second component, the Pressure Transducer (accessory), is an electromechanical device, containing sensors encased in a silicone custom mouth piece that connects to the SwallowSTRONG Device and allows the SwallowSTRONG enables recording of therapy sessions.

A speech-language pathologist fits the transducer and prescribes a therapy protocol. The patient holds the transducer against the hard palate of their mouth and applies isometric pressure with different parts of their tongue against the transducer sensors. This exercise strengthens intrinsic and extrinsic lingual muscles.

The SwallowSTRONG System is only useful as part of oropharyngeal strengthening therapy for patients with dysphagia or swallowing dysfunction. Although the SwallowSTRONG System is used in a variety of settings, most therapy sessions take place in the patient's home with no clinician present. The first component, the SwallowSTRONG Device, is typically used by a single patient for 8-12 weeks, then is clean/refurbished and provided to another patient. The second component, the Pressure Transducer (accessory), is single-patient-use and withstands approximately 70-110 uses, over the duration of therapy.

The applicant comments that no existing HCPCS code accurately describes the components of the SwallowSTRONG System.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the SwallowSTRONG device and pressure transducer has not been approved, because the device and the transducer are part of a service. Payment for that service includes payment for all components of the SwallowSTRONG system, device, and transducer, if used.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision. The speaker claimed that the SwallowSTRONG System "is not well described as a therapy expense because it is predominately used in the patient's home with no clinician present". The main site of care (86%) occurs in the patients' homes. "Further, both the system and accessory are reused many times, serve a medical purpose, and are not useful in the absence of an illness, thus meeting the criteria for Durable Medical Equipment." The speaker reiterated the original request to establish two new codes: one to describe the Swallowing rehab system, and one to describe a pressure transducer for use with the system. The speaker also reiterated the request to consider the system and the transducer to be DME.

HCPCS Public Meeting Agenda Item # 9

Wednesday, June 2, 2016

Application# 16.092

TOPIC

Repeat and related requests to establish two new Level II HCPCS codes to identify the components of the inFlow™ Intraurethral Valve Pump system and activator.

Applicant's suggested language:

16.092: "LXXX1, Female urinary prosthesis, temporary, with delivery system".

16.093: "LXXX2, Activator for female urinary prosthesis".

BACKGROUND

Two separate, related requests were submitted on behalf of Vesiflo Inc., to establish a total of two new codes, one each to identify the two components of the inFlow™ Intraurethral Valve Pump system. According to the applicant, the inFlow Intraurethral Valve pump system is a urinary "prosthesis" comprised of the inFlow device, and the Activator. The inFlow device is a sterile, single-use, intraurethral valve-pump that is inserted into the female urethra. As a prosthetic device, the inFlow compensates for the inability of women with impaired detrusor contractility (IDC) to generate bladder pressure by pumping the urine out of the urinary bladder, allowing almost normal use of a toilet. Other benefits include reduced rates of infection and encrustation, as well as improved quality of life.

The inFlow urinary prosthesis device is indicated for use by adult females with permanently impaired detrusor contractility of neurologic origin—a condition where patients care unable to empty their bladder. The inFlow device is a 3-7cm long magnetic pump encased in a silicone tube that has flexible stays to anchor the device at the bladder neck. The pump is packaged with a disposable introducer. Device sizing and initial insertion is performed by a physician. Device insertion is similar to that of a urinary catheter. The device is replaced every 29 days (essentially monthly) by the patient or a caregiver.

The activator is a hand-held, patient-operated remote control that operates the internal valve-pump mechanism in the Inflow device. The activator comes with a base station for charging its internal battery. The user sits on the commode, uses the remote control activator to activate the valve pump, which pumps urine from the bladder through the urethra to empty the bladder.

The applicant comments that the inFlow Valve Pump and activator are new technology and there are no existing HCPCS codes that describe the inFlow device or the activator. A code is not needed for the replacement battery.

PRELIMINARY HCPCS CODING RECOMMENDATION

These requests to establish new Level II HCPCS codes to separately identify the Inflow Valve-Pump and Activator have not been approved. Reported sales volume is insufficient to support a request for a revision to the national code set. In accordance with HCPCS coding criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity, so that adding new codes enhances the efficiency of the system and justifies the administrative burden of adding the codes. Existing code A4335 "Incontinence supply; miscellaneous" is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code applies to this device, including the catheter, remote control, batteries, and replacement catheters, if covered. Pricing = 46.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision and disputed the rationale behind it. The speaker stated that "the inFlow is for a very specific patient population and high volume may never be reached. InFlow is limited to women with impaired detrusor contractility (IDC) of neurologic original. These women have an acute need for better treatment options and we ask that their level of need be considered in code issuance." Moreover, "the inFlow has shown significant therapeutic benefits" compared to using intermittent or indwelling urinary catheters in terms of fewer Urinary Tract Infections. The speaker concluded that without a new HCPCS code, "very few women will benefit" from this product. The speaker reiterated the requests (from 16.092 and 16.093) for two new codes and suggested that CMS consider the inFlow system to be a prosthesis.

HCPCS Public Meeting Agenda Item # 9

Wednesday, June 2, 2016

Application# 16.093

TOPIC

Repeat and related requests to establish two new Level II HCPCS codes to identify the components of the inFlow™ Intraurethral Valve Pump system and activator.

Applicant's suggested language:

16.092: "LXXX1, Female urinary prosthesis, temporary, with delivery system".

16.093: "LXXX2, Activator for female urinary prosthesis".

BACKGROUND

Two separate, related requests were submitted on behalf of Vesiflo Inc., to establish a total of two new codes, one each to identify the two components of the inFlow™ Intraurethral Valve Pump system. According to the applicant, the inFlow Intraurethral Valve pump system is a urinary "prosthesis" comprised of the inFlow device, and the Activator. The inFlow device is a sterile, single-use, intraurethral valve-pump that is inserted into the female urethra. As a prosthetic device, the inFlow compensates for the inability of women with impaired detrusor contractility (IDC) to generate bladder pressure by pumping the urine out of the urinary bladder, allowing almost normal use of a toilet. Other benefits include reduced rates of infection and encrustation, as well as improved quality of life.

The inFlow urinary prosthesis device is indicated for use by adult females with permanently impaired detrusor contractility of neurologic origin—a condition where patients care unable to empty their bladder. The inFlow device is a 3-7cm long magnetic pump encased in a silicone tube that has flexible stays to anchor the device at the bladder neck. The pump is packaged with a disposable introducer. Device sizing and initial insertion is performed by a physician. Device insertion is similar to that of a urinary catheter. The device is replaced every 29 days (essentially monthly) by the patient or a caregiver.

The activator is a hand-held, patient-operated remote control that operates the internal valve-pump mechanism in the Inflow device. The activator comes with a base station for charging its internal battery. The user sits on the commode, uses the remote control activator to activate the valve pump, which pumps urine from the bladder through the urethra to empty the bladder.

The applicant comments that the inFlow Valve Pump and activator are new technology and there are no existing HCPCS codes that describe the inFlow device or the activator. A code is not needed for the replacement battery.

PRELIMINARY HCPCS CODING RECOMMENDATION

These requests to establish new Level II HCPCS codes to separately identify the Inflow Valve-Pump and Activator have not been approved. Reported sales volume is insufficient to support a request for a revision to the national code set. In accordance with HCPCS coding criteria as published on CMS' HCPCS website, there must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity, so that adding new codes enhances the efficiency of the system and justifies the administrative burden of adding the codes. Existing code A4335 "Incontinence supply; miscellaneous" is available for assignment by insurers if they deem appropriate.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

The payment rules associated with the existing code applies to this device, including the catheter, remote control, batteries, and replacement catheters, if covered. Pricing = 46.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision and disputed the rationale behind it. The speaker stated that "the inFlow is for a very specific patient population and high volume may never be reached. InFlow is limited to women with impaired detrusor contractility (IDC) of neurologic original. These women have an acute need for better treatment options and we ask that their level of need be considered in code issuance." Moreover, "the inFlow has shown significant therapeutic benefits" compared to using intermittent or indwelling urinary catheters in terms of fewer Urinary Tract Infections. The speaker concluded that without a new HCPCS code, "very few women will benefit" from this product. The speaker reiterated the requests (from 16.092 and 16.093) for two new codes and suggested that CMS consider the inFlow system to be a prosthesis.

HCPCS Public Meeting Agenda Item # 10

Wednesday, June 2, 2016

Application# 16.094

TOPIC

Request to establish a new Level II HCPCS code to identify a vibrotactile feedback device, Trade Name: WalkJoy.

Applicant's suggested language: "EXXXX – Vibrotactile stimulation device system, complete assembly, pair."

BACKGROUND

WalkJoy, Inc. submitted a request to establish a new code to identify the WalkJoy device. According to the applicant, the WalkJoy is a vibrotactile stimulation biofeedback device. It is a noninvasive, wearable gait and balance restoration device supplied as a pair of assemblies (left and right), each consisting of a solid state device which attaches to velcro straps and a USB/AC charging unit. The WalkJoy is worn around the lower leg, centered on the front of the tibia, directly below the knee.

Upon heel strike during gait, the device delivers vibrotactile stimulation intended to provide a secondary signal to healthy nerves in the lower leg toward reestablishment of the human sensor-motor loop, thereby aiding in the restoration of gain and balance loss due to any form of neuropathy. The WalkJoy employs technology based on "sensory stimulation," i.e., the ability of the central nervous system to use an alternative sensory stimulation to restore motor function.

The WalkJoy is indicated for patients who have peripheral neuropathy. Peripheral nerve damage produces loss of sensation and an inability to control muscles, which leads to poor gait, balance, increased falls and foot ulcers.

The applicant comments that a new code is warranted because there are no similar products on the market, and there are no existing HCPCS codes that identify vibrotactile stimulation biological feedback devices, gait resolution, or the use of this technology for proprioceptive gait improvements and fall prevention.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the WalkJoy device (vibrotactile stimulation biofeedback device) has not been approved. This product is an integral part of a procedure, and payments for that service includes payment for the WalkJoy device if it is used.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision that the product is included in a biofeedback procedure. The speaker claimed that "WalkJoy is not part of a procedure." Rather, "WalkJoy is a stand-alone medical device" on the basis that it is classified by the FDA as a Class II (biofeedback) device. The speaker discussed indications for use of the WalkJoy, such as "peripheral neuropathy, Parkinson's [disease] and Multiple Sclerosis," stating that the WalkJoy "improves balance, gait and helps reduce falls." The speaker requested "either a new code or a modifier," and a fee of "$3,500.00 per pair, as 95% of the time our patient's condition is bilateral". The speaker also stated that "reimbursement will enable [the manufacturer] to help more patients and help bring down the CMS costs associated with falls." The speaker made comparisons to electronic stimulation devices (that do not apply).

HCPCS Public Meeting Agenda Item # 11

Wednesday, June 2, 2016

Application# 16.095

TOPIC

Repeat request to establish a new Level II HCPCS code to identify a non-invasive, portable, table-top arm rehabilitation device, Trade Name: Tailwind™.

Applicant's suggested language: "E18XX – Dynamic, upper extremity paralysis, bilateral arm rehabilitation, repetitive movement device with auditory cues and range of motion adjustments, includes all accessories and components".

BACKGROUND

Encore Path, Inc. submitted a request to establish a new Level II HCPCS code to identify the Tailwind. According to the applicant, the Tailwind is used in arm rehabilitation and therapy for stroke or traumatic brain injury survivors, resulting in moderate-to-severe arm paralysis on one side of the body. The device includes clamping pods for table-top placement, bilateral chest support, arm tracks, end stops, a counter and a metronome. The user is seated in front of the device. When cued by the metronome, the user moves the handles along the track, and repeats the movement forward and back. The end stops can be adjusted for progressively more challenging positions and increase range of motion. The Tailwind incorporates neuro-functional couplings and controlled, repetitive movement to enable reactivation of central neuromuscular pathways responsible for arm movement. The device has been shown to increase hemispheric activation and permanently improve arm motor function and range of motion.

The device is intended for use in the improvement of arm movement and function in the paretic arm of stroke patients with hemi-paresis. The device can used independently in the home setting or with the aid of a caregiver/therapist. The Tailwind comes with a standard 90 Day Limited Warranty that is solely applicable to the original purchaser of the Tailwind product.

The applicant comments that a new code is warranted because no existing permanent HCPCS codes identifies the Tailwind. Available HCPCS codes for DME flexion/extension device technologies are limited to static and dynamic devices for a single joint or one anatomical body part, and do not include codes for the rehabilitation of the entire upper extremity function.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Tailwind has not been approved. Existing code A9300 "EXERCISE EQUIPMENT" adequately describes exercise equipment and is available for assignment by insurers if they deem appropriate to report the Tailwind device.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item # 12

Wednesday, June 2, 2016

Application# 16.008

TOPIC

Two separate, related requests to establish a total of five new Level II HCPCS drug codes to identify polymerized, cross-linked Sucralfate products, including ProThelial mucositis paste in two sizes; and Orafate Oral Anti-Inflammation paste in three sizes.

Applicant's suggested language:

16.008:

JXXX1 Mucositis Paste, 500ml-Polymerized Cross-linked Sucralfate, ProThelial 10%

JXXX2 Mucositis Paste, 120ml-Polymerized Cross-linked Sucralfate, ProThelial 10%

16.072:

JXXX3 Oral Anti-Inflammation Paste, 3 mL Polymerized Cross-linked Sucralfate

JXXX4 Oral Anti-Inflammation Paste, 30 mL Polymerized Cross-linked Sucralfate

JXXX5 Oral Anti-Inflammation Paste, 90 mL Polymerized Cross-linked Sucralfate

BACKGROUND

Mueller Medical International Corporation submitted two separate, related requests to establish a total of five new codes to identify different sizes of ProThelial™ Mucositis paste and Orafate Oral Anti-Inflammation paste. Both Trade Names ProThelial and Orafate Sucralfate Malate Paste share the same FDA 501K marketing clearance and have identical indications for use: forming "a protective layer over the oral mucosal surface which allows it to protect against further irritation and relieve pain. The paste may be used in the management of mouth lesions of all types including aphtous ulcer, stomatitis, mucositis, minor lesions, chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery". According to the applicant, these products are classified by the FDA as devices and are not drugs or biologicals, yet their active component is a drug.

ProThelial mucositis paste is marketed for chemotherapy-induced mucositis. It is applied, gargled, then expectorated or swallowed if so instructed by the oncologist. For prevention or elimination of moderate mucositis (Grade 1-2), 2.5 to 5 mL of paste is applied to all surfaces of the mouth every 8 hours for the first day, then every 12 hours thereafter. For prevention or elimination of severe mucositis (Grade 3-4), 5 mL of paste is applied to all surfaces of the mouth

every 8 hours for the first day, then every 12 hours thereafter. Prothelial contains 10% polymerized Sucralfate and is supplied as a multi-unit of 4 individually packaged 125 mL bottles; and in single multi-use 120 mL bottles.

Orafate Oral Anti-Inflammatory paste is marketed for use for soft-tissue inflammation related to infection, trauma, and dental and oral surgery procedures. It also contains 10% polymerized Sucralfate and is supplied as a paste in: a 3 mL single-use unit; a 30 mL multi-use unit; and a 90 mL multi-use unit. The 3 mL unit is applied in its entirety in-office by practitioners (e.g., at the site of dental extraction or dental scaling, planing or cleaning). The multi-use bottles are for home use. 1.25 to 2.5 mL is brushed on.

Both products are patient self-administered.

The applicant comments that new codes are warranted because there are no existing HCPCS codes that describe ProThelial or Orafate products.

PRELIMINARY HCPCS CODING RECOMMENDATION

These requests to establish new Level II HCPCS codes to separately identify a variety of sizes of ProThelial and Orafate products have not been approved. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish new HCPCS code to identify the products that are the subject of these requests.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for these items. Written comments were received, disagreeing with CMS' preliminary decision. The written comments stated that 60,000 cancer patients die prematurely each year due to poorly managed chemoradiation-induced mucositis. Persons afflicted with mucositis that do not respond to other products would respond to ProThelial. As such, "it would appear that there is a quantifiable, real world national program operating need for ProThelial necessitating specific Medicare-assigned HCPCS codes. And given that there is no non-antibiotic therapeutic option that addresses healing of disorders of oral inflammation, Orafate should be assigned specific Medicare HCPCS codes." The written comments also suggest that CMS' responses vary based on which manufacturer sponsors the request.

HCPCS Public Meeting Agenda Item # 12

Wednesday, June 2, 2016

Application# 16.072

TOPIC

Two separate, related requests to establish a total of five new Level II HCPCS drug codes to identify polymerized, cross-linked Sucralfate products, including ProThelial mucositis paste in two sizes; and Orafate Oral Anti-Inflammation paste in three sizes.

Applicant's suggested language:

16.008:

JXXX1 Mucositis Paste, 500ml-Polymerized Cross-linked Sucralfate, ProThelial 10%

JXXX2 Mucositis Paste, 120ml-Polymerized Cross-linked Sucralfate, ProThelial 10%

16.072:

JXXX3 Oral Anti-Inflammation Paste, 3 mL Polymerized Cross-linked Sucralfate

JXXX4 Oral Anti-Inflammation Paste, 30 mL Polymerized Cross-linked Sucralfate

JXXX5 Oral Anti-Inflammation Paste, 90 mL Polymerized Cross-linked Sucralfate

BACKGROUND

Mueller Medical International Corporation submitted two separate, related requests to establish a total of five new codes to identify different sizes of ProThelial™ Mucositis paste and Orafate Oral Anti-Inflammation paste. Both Trade Names ProThelial and Orafate Sucralfate Malate Paste share the same FDA 501K marketing clearance and have identical indications for use: forming "a protective layer over the oral mucosal surface which allows it to protect against further irritation and relieve pain. The paste may be used in the management of mouth lesions of all types including aphtous ulcer, stomatitis, mucositis, minor lesions, chafing and traumatic ulcers, abrasions caused by braces and ill-fitting dentures, and lesions associated with oral surgery". According to the applicant, these products are classified by the FDA as devices and are not drugs or biologicals, yet their active component is a drug.

ProThelial mucositis paste is marketed for chemotherapy-induced mucositis. It is applied, gargled, then expectorated or swallowed if so instructed by the oncologist. For prevention or elimination of moderate mucositis (Grade 1-2), 2.5 to 5 mL of paste is applied to all surfaces of the mouth every 8 hours for the first day, then every 12 hours thereafter. For prevention or

elimination of severe mucositis (Grade 3-4), 5 mL of paste is applied to all surfaces of the mouth every 8 hours for the first day, then every 12 hours thereafter. Prothelial contains 10% polymerized Sucralfate and is supplied as a multi-unit of 4 individually packaged 125 mL bottles; and in single multi-use 120 mL bottles.

Orafate Oral Anti-Inflammatory paste is marketed for use for soft-tissue inflammation related to infection, trauma, and dental and oral surgery procedures. It also contains 10% polymerized Sucralfate and is supplied as a paste in: a 3 mL single-use unit; a 30 mL multi-use unit; and a 90 mL multi-use unit. The 3 mL unit is applied in its entirety in-office by practitioners (e.g., at the site of dental extraction or dental scaling, planing or cleaning). The multi-use bottles are for home use. 1.25 to 2.5 mL is brushed on.

Both products are patient self-administered.

The applicant comments that new codes are warranted because there are no existing HCPCS codes that describe ProThelial or Orafate products.

PRELIMINARY HCPCS CODING RECOMMENDATION

These requests to establish new Level II HCPCS codes to separately identify a variety of sizes of ProThelial and Orafate products have not been approved. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish new HCPCS code to identify the products that are the subject of these requests.

PRELIMINARY MEDICARE PAYMENT RECOMMENDATION

No separate Medicare payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for these items. Written comments were received, disagreeing with CMS' preliminary decision. The written comments stated that 60,000 cancer patients die prematurely each year due to poorly managed chemoradiation-induced mucositis. Persons afflicted with mucositis that do not respond to other products would respond to ProThelial. As such, "it would appear that there is a quantifiable, real world national program operating need for ProThelial necessitating specific Medicare-assigned HCPCS codes. And given that there is no non-antibiotic therapeutic option that addresses healing of disorders of oral inflammation, Orafate should be assigned specific Medicare HCPCS codes." The written comments also suggest that CMS' responses vary based on which manufacturer sponsors the request.