Centers for Medicare & Medicaid Services (CMS)
HCPCS Public Meeting Summary Report for:
Supplies and Other Public Meeting
Tuesday, June 21, 2005

Public Meeting Introduction and Overview

Robin Williams, CMS Office of Operations Management, moderated the meeting. Approximately 45 people attended. The agenda included 23 items.

Cindy Hake provided an overview of the public meeting process and the overall HCPCS process. She also discussed the survey of stakeholders regarding needed changes to the HCPCS process, the nature of responses to the survey, and the nature of changes already made, as well as pending changes, included in the reformation of the HCPCS process. Monitor the HCPCS world-wide website for announcement of changes to the HCPCS coding process at www.cms.hhs.gov/medicare/hcpcs.

Joel Kaiser presented an educational overview of the variety of methods used for setting the payment amount for items, and when the different methods are used. This overview was also provided as a written attachment to the agenda. For additional information, the DME payment rules are located at Section 1834(a) of the Social Security Act. The Medicare fee schedule for DME, Prosthetics, Orthotics and Supplies, and background information, can be accessed and downloaded free of charge at: http://cms.hhs.gov/providers/pufdownload/default.asp#dme.

CMS HCPCS Public Meetings provide an opportunity for CMS to share its preliminary coding decisions and payment recommendations, and an opportunity for interested parties to make oral presentations and submit written comments in reaction to CMS' these coding and pricing recommendations.

Prior to the Public Meetings the CMS HCPCS workgroup meets to review the coding requests on the public meeting agenda, and to make a preliminary coding decision. CMS also makes preliminary decisions regarding the applicable 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 included in the public meeting agendas.

Following the public meeting, the CMS HCPCS workgroup will reconsider its preliminary coding decisions based on the input heard at the Public Meetings. Afterwards, the workgroup will decide on its final recommendations. 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.

HCPCS Public Meetings are not workgroup meetings. No final decisions are made at the public meetings. All requestors will be notified in writing, in early November, of the workgroup's final decision regarding the HCPCS code request(s) they submitted.

The process for developing agendas and speaker lists for the public meetings, and Guidelines for Proceedings at CMS' Public Meetings for new supplies are posted on the official HCPCS world wide web site at: http://cms.hhs.gov/medicare/hcpcs/default.asp. The standard application form for requesting a modification to the HCPCS Level II Coding System, along with instructions for completion and background information regarding the HCPCS Level II coding process is available on the same web site.

Public Meeting Summary

The following information includes a detailed summary of each request on the Public Meeting Agenda, along with CMS' preliminary decisions and rationale, and summaries of presentations made by primary speakers.

Meeting Agenda Item #1
June 21, 2005
HCPCS Request #05.142

Background/Discussion:
Michele Federico of Health Care Excel has submitted a request to establish a code for an ostomy clamp, Trade Name: Ostomy Clamp. According to the requestor, an ostomy clamp is a closure accessory used to prevent the unwanted spillage of an open-ended ostomy bag. They are supplied with open-ended ostomy bags and additional clamps may be purchased separately.

CMS HCPCS Workgroup Preliminary Decision: To establish a new "A" code.

A???? Ostomy clamp, any type, each.

The ostomy clamp should be included with the original purchase of the bag. A new code will be established for replacement only.

There was no Primary Speaker for this item.

Meeting Agenda Item #2
June 21, 2005
HCPCS Request #05.143

Background/Discussion:
Deanna Eaves of Hollister Incorporated has submitted a request to establish an "A" code and suggests the following language: "ostomy skin barrier, solid, 4x4 inches or equivalent, extended wear, with built-in convexity", Trade Name: ADAPT Convex Barrier Rings. According to the requestor, ADAPT Convex Barrier Rings are circular convex barriers made from an extended wear barrier material that will stand up to corrosive discharge. They are designed to protect the peristomal skin from contact and potential breakdown from corrosive discharge. They are available in three inner diameters: 20 mm, 30 mm, and 40 mm. The rings are designed to provide the end-user or clinician with the ability to develop customized convexity, which may improve the skin protection and wear time for the individual with the ostomy.

CMS HCPCS Workgroup Preliminary Decision: To establish a new "A" code.

A???? Ostomy skin barrier, solid 4X4 or equivalent, extended wear, with built-in convexity, each.

Revise A4372 which currently reads (ostomy skin barrier, solid 4X4 or equivalent, with built-in convexity, each), to instead read: Ostomy skin barrier, solid 4X4 or equivalent, standard wear, with built-in convexity, each.

Use the new A code to describe extended wear ostomy skin barrier. Consult the policies of individual payers for their definition of extended wear.

Primary Speaker – Deanna Eaves, on behalf of Hollister Incorporated, commended the workgroup and agreed with its decision to establish a new "A" code for an ostomy extended wear, convex barrier. In addition, the modification to the language for A4372 to include the words "standard wear" will assist providers in properly coding these barriers.

Meeting Agenda Item #3
June 21, 2005
HCPCS Request #05.164

Background/Discussion:
Deanna Eaves of Hollister submitted a request to revise existing code A4413 OSTOMY POUCH, DRAINABLE, HIGH OUTPUT, FOR USE ON A BARRIER WITH FLANGE (2 PIECE SYSTEM), WITH FILTER, EACH to change the words "with filter" to instead read "with or without filter" to accurately describe drainable high output pouches that do not include a filter. According to the requester, CenterPointLock is a drainable ostomy pouch that allows for increased output. It is transparent and has a capacity greater than 0.75 liters. CenterPointLock is used for people with an ostomy or surgically created opening for removal of bodily waste. This pouch is specifically designed for liquid-type stools that may be more common in an ileostomate or a colostomate who is experiencing diarrhea. It does not have a filter because filters can be easily compromised if allowed to get wet; and it does not have an anti-reflux valve because such valves may become clogged with stool. CenterPointLock is applied to the body using a connection to a barrier with flange. It is available in three flange sizes.

CMS HCPCS Workgroup Preliminary Decision: To establish a new "A" code.

A???? Ostomy pouch, drainable, high output, for use on a barrier with flange (2 piece system), without filter, each.

Primary Speaker – Deanna Eaves, on behalf of Hollister Incorporated, agrees with the creation of a new code for high output pouches that do not have a filter.
Our CenterPointLock high output pouch was designed to accommodate liquid-type stools which could easily compromise a filter. In addition to the new code creation, we would like to point out that the ostomy policy coding guidelines definition of a high output pouch specifically states that the product contains an anti-reflux valve. We would like to request that this specification be removed from the coding guidelines since anti-reflux valves can become clogged with stool. Additionally, the coding guidelines state that a high output pouch is part of a 2 piece system. We would like to request that this verbiage be removed from the guidelines and that the determination of a 1 piece or 2 piece system be left at the HCPCS code level. In this way, we pave the way for a 1 piece high output system and do not limit ourselves by the coding guidelines section of the policy. We feel it is important to offer alternatives to the clinician in order for them to make a decision about what type of high output pouch will work best for each individual beneficiary's situation.

Meeting Agenda Item #4
June 21, 2005
HCPCS Request #05.145

Background/Discussion:
Mary Erslon, RN, MSN, of Tyco Healthcare/Nellcor Puritan Benefit has submitted a request to establish a code for a specialized/custom-fabricated tracheostomy tube, Trade Name: Shiley®. According to the requestor, Shiley specialized/custom tracheostomy tubes are custom fabricated artificial airways that are constructed of medical grade materials. The applicant claims that they are custom fabricated for specialized length, curvature, fenestration, and cuffs for difficult to fit patients whose needs cannot be met with a standard tracheostomy tube. Specific airway requirements are measured by the patient's physician and submitted to Shiley for fabrication of a specialized/customized tracheostomy tube on an as-ordered basis. Tracheostomy tubes are artificial airways inserted into the trachea to relieve a breathing obstruction.

CMS HCPCS Workgroup Preliminary Decision: To use existing codes A7520 Tracheostomy/laryngectomy tube non-cuffed, polyvinylchloride (PVC), silicon or equal, each or A7521 Tracheostomy/laryngectomy tube cuffed, polyvinylchloride (PVC), silicone or equal, each (as appropriate, based on whether the tube is cuffed or non-cuffed).

Existing codes, A7520 and A7521, adequately describe cuffed and non-cuffed tracheostomy laryngectomy tubes. In addition, information provided does not support the claim that this item is custom fabricated for an individaul patient (as opposed to a prefabricated item being cut/adjusted and assembled to fit a patient). There are no significant therapeutic distinctions between the category of item described in these codes and the items in the coding request. The use of S1002, E1399, or any other miscellaneous codes to identify these items is inappropriate. The CMS HCPCS Workgroup would be happy to consider a future HCPCS code request including information that clearly demonstrates that the products are custom fabricated.

There was no Primary Speaker for this item.

Meeting Agenda Item #5
June 21, 2005
HCPCS Request #05.146

Background/Discussion:
Michelle Ford, of Helix Medical dba, InHealth Technologies, has submitted a request to change the verbiage of existing code A4364, and a request to establish a new code for a hypoallergenic adhesive, Trade Name: Blom-Singer Silicone Adhesive. Current A4364 verbiage: ADHESIVE, LIQUID OR EQUAL, ANY TYPE, PER OZ. Requested verbiage: "Adhesive, liquid or equal, for use near or around airways but not for inhalation/ingestion, per oz". Suggested language for requested new code: "Adhesive, liquid or equal, hypoallergenic, for use with tracheostomy, per oz". According to the requestor, Blom-Singer Silicone Adhesive is used to safely attach adhesive foam and tape discs to the skin. The adhesive ensures a tight seal to prevent air leaks, and leakage of mucous and must be applied daily or multiple times daily. It is intended for use by laryngectomees who have undergone surgical removal of their voice box/larynx and have undergone a tracheoesophageal puncture (TEP) for voice restoration. Currently, A4364 is used to describe the product; however it states "any type". The requestor feels that the adhesives used to create and price this code were developed for colostomies, ileostomies, or urinary stomas and their ingredients did not have to be tested/safe for inhalation. The requestor claims that the general description of the code may also confuse suppliers and they may offer an adhesive product to a tracheostomy patient that is not safe for them to use.

CMS HCPCS Workgroup Preliminary Decision: To use existing code A4364 Adhesive, liquid or equal, any type, per ounce.

Existing code, A4364, adequately describes adhesive, liquid or equal. Varying properties of products within this code category, such as inhalable, ingestable and hypoallergenic, do not alter the primary function of the product to act as an adhesive. And, since the code specifies "any type", hypoallergenic adhesives are included under this code. No insurer indentified a national program operating need to alter the existing code set to differentiate liquid (or equal) adhesive based on whether it is ingestable or hypoallergenic. The FDA has either reviewed and approved or has exempted from review various products in this category, taking into consideration consumer safety.

Primary Speaker – Jennifer Hutter, on behalf of Helix Medical, disagreed with the preliminary coding decision, claiming that:

- There are differences in adhesive used for tracheostoma and those used for skin adhesion;
- CMS has set precedent for coding other silicone devices/supplies.
- Ms. Hutter from the orginal request proposed verbiage for the requested code that is different
    - AXXXX—Adhesive, liquid or equal, silicone-based for use with tracheostomies, per oz.

Meeting Agenda Item #6
June 21, 2005
HCPCS Request #05.147

Background/Discussion:
Michelle Ford of Helix Medical dba, InHealth Technologies has submitted a request to delete A7506 ADHESIVE DISC FOR USE IN A HEAT AND MOISTURE EXCHANGE SYSTEM AND/OR WITH TRACHEOSTOMA VALVE, ANY TYPE, EACH and create two new codes to separately identify two types of adhesive discs (paper and foam). According to the requestor, the code that is currently used to describe this product, A7506, does not provide sufficient reimbursement as it is priced for the paper tape discs only, and not for the foam tape discs. The requested language for the new codes is: **AXXXX** Adhesive foam tape disc, for use in heat and moisture exchange system and/or with a tracheostoma valve, each. **AXXXX** Adhesive paper tape disc, for use in a heat and moisture exchange system and/or with a tracheostoma valve, each.

CMS HCPCS Workgroup Preliminary Decision: To use existing code A7506 (Adhesive disc for use in a heat and moisture exchange system and/or with tracheostoma valve, any type each) to identify paper and foam discs.

Existing code, A7506, adequately describes adhesive discs of any type. Code A7506 does not specify the type of material, therefore both paper and foam discs are included in this code. The difference in material presented (paper vs: foam), does not alter the function or purpose of the device.

Primary Speaker – Jennifer Hutter, on behalf of Helix Medical, disagreed with the preliminary coding decision; asked that the difference in material be recognized; claimed that foam (e.g., vs. paper can be medically indicated and reiterated original request for 2 new codes.

Meeting Agenda Item #7
June 21, 2005
HCPCS Request #05.148

Background/Discussion:

Michelle Ford of Helix Medical dba, InHealth Technologies has submitted a request to discontinue A7503 FILTER HOLDER OR FILTER CAP, REUSABLE, FOR USE IN A TRACHEOSTOMA HEAT AND MOISTURE EXCHANGE SYSTEM, EACH, and to establish three new codes. Requested language is as follows:

AXXXX Filter cap, reusable up to one month, for use in a tracheostoma heat and moisture exchange system, each

AXXXX Filter cap, reusable for six months or longer, for use in a tracheostoma heat and moisture exchange system, each

AXXXX Filter holder, nonintegrated, reusable, for use in a tracheostoma heat and moisture exchange system, each

According to the requestor, there is a difference in the length of durability of the products grouped under A7503. Some of the caps can only be used for one month, whereas some of the caps can be used for up to one year. This difference in material and durability also results in a difference in cost. The requestor claims that code A7503 does not provide sufficient reimbursement as it is priced for the one-month disposable caps only, and not a filter holder or cap that can be used up to a year. The requester also claims that A7507 FILTER HOLDER AND INTEGRATED FILTER WITHOUT ADHESIVE, FOR USE IN A TRACHEOSTOMA HEAT AND MOISTURE EXCHANGE SYSTEM, EACH describes a one-time use only filter and requests a new code to identify a non-integrated filter holder which serves as a combined filter and cap, and is expected to last 8-12 months.

CMS HCPCS Workgroup Preliminary Decision: To use existing code A7503 (filter holder or filter cap, reusable, for use in a tracheostoma heat and moisture exchange system, each) to identify non-integrated, reusable filter caps or holders. To use existing code A7509 (filter holder and integrated filter housing, and adhesive, for use as a tracheostoma heat and moisture exchange system each) to identify integrated filter caps.

Existing codes A7503 and A7509 adequately distinguish and describe non-integrated, reusable and integrated filter caps. The items that are the subject of this request, FDA 510K approved and marketed since 1992, were available and considered at the time these codes were originally established. No insurer identified a national program operating need to alter the existing code set to further distinguish items within the A7503 and A7509 code categories based on claims of differential longevity between products. Inquiries regarding reimbursement rates, such as those raised in your application should be directed to the individual insurer. For Medicare, contact CMS' Inherent Reasonableness authority. For Medicaid, contact the the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor. Reimbursement rate, by itself, is not a basis for a coding distinction.

Primary Speaker – Jennifer Hutter, on behalf of Helix Medical, disagreed with the preliminary decision claiming that the Workgroup previously made a code for the reusable caps and filter holders (A7503) and inserted the word “reusable”, therefore there must have been knowledge of the disposable version. Ms. Hutter reiterated the original request to establish 3 new codes to differentiate between filter caps based on varying duration of use; and filter holders.

Meeting Agenda Item #8
June 21, 2005
HCPCS Request #05.137

Background/Discussion:
Brad Selman of Coloplast A/S submitted a request to establish a code to distinguish hydrophilic intermittent urinary catheters from catheters made of other materials. According to the requester, SpeediCath® is a sterile, single use, hydrophilic-coated intermittent catheter that is pre-lubricated in sterile saline solution. The SpeediCath® hydrophilic coating, which consists of sterile water, is chemically bonded to the catheter, ensuring the coating is consistent and remains on the catheter throughout catheterization. The catheter is always optimally hydrated; consequently it is extremely slippery, extremely comfortable, and may cause less trauma to the urethral tissue than other catheters. SpeediCath® is designed for single use and must be discarded after one use. Because SpeediCath® is packaged in a sterile saline solution, and is pre-lubricated, users do not have to find water or squeeze a sachet to release water into the package, or apply a secondary lubricant. The applicant claims that "it may be medially necessary to use SpeediCath®, rather than a conventional catheter (i.e., a catheter that requires application of a lubricant) in a situation where a patient is susceptible to urinary tract infections, has a history of urethral trauma or infection, or requires sterile catheterization for some other reason". The applicant also claims that "Hydrophilic and conventional catheters are not functionally equivalent;" that "Hydrophilic technology may offer a safer, more hygienic form of intermittent catheterization and is appropriate for certain patients"; and suggests that access to Hydrophilic catheters is limited in the absence of a unique code to isolate catheters made with hydrophilic materials. This applicant distinguishes the SpeediCath from other hydrophilic catheters based on prelubrication without the need to immerse in water prior to use.

CMS HCPCS Workgroup Preliminary Decision: To use existing codes A4351 Intermittent urinary catheter, straight tip, with or without coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each or A4352 Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each (as appropriate).

Existing codes A4351 or A4352 (depending on whether the catheter is straight or coude tipped) adequately describe a category of intermittent catheters used to drain the urinary bladder. Chemical, physical, technological and cost differences between catheters made of hydrophilic catheters and catheters made of other materials do not change the primary function of the device, intermittent drainage of the urinary bladder. Clinical information provided does not demonstrate a difference in clinical indications or outcome based on use of catheters made of hydrophilic vs: other materials. No payer representative (Medicare, Medicaid, Private Insurer) of the CMS HCPCS Workgroup identified a national program operating need to alter the existing code set to distinguish catheters make with hydrophilic materials from catheters make with other materials. There are mechanisms within the HCPCS Level II code set that enable flexibility for individual

insurers or individual states to isolate hydrophilic catheters for tracking or differential payment if they so choose.

Primary Speaker – Andy Webb of ColoPlast. Coloplast A/S appreciates the HCPCS Workgroup's careful review of its coding request. However, respectfully disagreed with the Workgroup's preliminary decision in several key areas. The primary speaker's response addressed the following issues:

- Hydrophilic and conventional catheters are not functionally equivalent.
- Hydrophilic technology may result in both improved clinical outcomes and reduced cost of the healthcare system.
- Lack of a separate HCPCS code for hydrophilic urinary catheters may impede appropriate access for Medicare beneficiaries.
- Although mechanisms may exist to differentiate hydrophilic catheters for payment at the regional and local levels, these mechanisms are not used, effectively limiting access to hydrophilic catheters.

Primary speaker conclusions and recommendation to the HCPCS Workgroup:

- Inadequate coding to distinguish hydrophilic from conventional urinary catheters limits access to hydrophilic urinary catheters for vulnerable segments of the Medicare and Medicaid populations for whom these products are medically necessary and appropriate.
- The HCPCS Workgroup should establish a new, unique HCPCS code for hydrophilic urinary catheters.

Meeting Agenda Item #9
June 21, 2005
HCPCS Request #05.138

Background/Discussion:
Grant Bagley of Arnold & Porter LLP submitted a request to establish 3 new codes for hydrophilic single use urinary catheter, Trade Names: LoFric® Plus, LoFric® Cath-Kit™, LoFric® Ready-Kit, and LoFric® H20 (collectively, LoFric® Catheters(s)) and revise 3 existing codes A4351, A4352 and A4353. According to the requester, hydrophilic catheters such as the LoFric® Catheter employ a multi-layer construction. A LoFric® Catheter (except LoFric® Plus) has a core of medical-grade polyvinyl chloride (PVC) and an outermost layer of polyvinylpyrrolidone (PVP) and sodium chloride (NaC1). This outer PVP/NaC1 layer is integral to the catheter and covers all external catheter surfaces that contact the urinary tract. The PVP/NaC1 attracts a layer of water that uniformly adheres to all external catheter surfaces. This bound water makes the catheter extremely slippery, allowing the catheter to move in the urinary tract with minimal friction and abrasion. The requester claims that there are "functional, chemical, physical technological and cost differences between hydrophilic and conventional catheters; differences in instructions for use; that the lack of unique codes describing hydrophilic catheters limits insurers' ability to track, process claims for and pay adequately for hydrophilic catheters and therefore limits patient access. Based on these claims, the requester suggests the addition of 3 new codes to describe hydrophilic catheters and insertion supplies; and the revision of 3 existing codes (A4351-A4353) as follows, (where underlined text is added and struck through text is deleted):

1) A4351 INTERMITTENT URINARY CATHETER; STRAIGHT TIP, WITH OR WITHOUT COATING (TEFLON, SILICONE, OR SILICONE ELASTOMER, ~~OR HYDROPHILIC, ETC.~~)
2) A4352 INTERMITTENT URINARY CATHETER; COUDE (CURVED) TIP, WITH OR WITHOUT COATING (TEFLON, SILICONE, OR SILICONE ELASTOMER, ~~OR HYDROPHILIC, ETC.~~)
3) A4353 INTERMITTENT URINARY CATHETER, CONVENTIONAL WITH INSERTION SUPPLIES

Request the following "A" codes be established:
1) Axxxx INTERMITTENT URINARY CATHETER; STRAIGHT TIP, HYDROPHILIC
2) Axxxx INTERMITTENT URINARY CATHETER; COUDE (CURVED) TIP, HYDROPHILIC
3) Axxxx INTERMITTENT URINARY CATHETER, HYDROPHILIC, WITH INSERTION SUPPLIES

CMS HCPCS Workgroup Preliminary Decision: To use existing codes A4351 Intermittent urinary catheter, straight tip, with or without coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each or A4352 Intermittent urinary catheter;

coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each (as appropriate).

Existing codes A4351 or A4352 (depending on whether the catheter is straight or coude tipped) adequately describe a category of intermittent catheters used to drain the urinary bladder. Chemical, physical, technological and cost differences between catheters made of hydrophilic catheters and catheters made of other materials do not change the primary function of the device, intermittent drainage of the urinary bladder. Clinical information provided does not demonstrate a difference in clinical indications or outcome based on use of catheters made of hydrophilic vs: other materials. No payer representative (Medicare, Medicaid, Private Insurer) of the CMS HCPCS Workgroup identified a national program operating need to alter the existing code set to distinguish catheters make with hydrophilic materials from catheters make with other materials. There are mechanisms within the HCPCS Level II code set that enable flexibility for individual insurers or individual states to isolate hydrophilic catheters for tracking or differential payment if they so choose.

Primary Speaker – Grant Bagley of Arnold & Porter LLP, disagreed with the workgroup's preliminary decision and provided the following list of claims and objections:

- The chemical, physical, technological, and cost differences between hydrophilic and conventional catheters should be sufficient to grant unique codes.
- Hydrophilic and conventional catheters are no more functionally equivalent than other products that have unique HCPCS codes (for instance, straight and coude catheters).
- Astra Tech has demonstrated differences in clinical indications and outcomes between hydrophilic and conventional catheters.
- Astra Tech should not have to demonstrate clinical differences because: (1) other products, without clinical differences, have been granted HCPCS codes; and (2) these are coverage not coding issues.
- Payors, such as Michigan Medicaid, have identified their need for unique HCPCS codes for hydrophilic catheters.
- Existing coding mechanisms, such as "U modifiers," are insufficient due to HIPAA concerns and private insurers' inability to use these modifiers.
- Without unique HCPCS codes, claims cannot be analyzed for outcomes data comparing hydrophilic and conventional catheters.
- The number of HCPCS Level II codes is virtually limitless (over 60 million), so there is no need to be so reluctant to award new codes.
- Current codes encourage unsafe off label use in the Medicare population with no scientific support.
- Current coding sets up confusing and unworkable claims processing schemes.

Meeting Agenda Item #10
June 21, 2005
HCPCS Request #05.139

Background/Discussion:
Clarke Scherff of the Mentor Corporation has submitted a request to 1) modify existing codes A4351 and A4352, removing the reference to hydrophilic catheters and 2) create new codes for straight tip and coude (curved) tip hydrophilic catheters.
According to the requestor, the Self Cath® is designed for single use, intermittent urethral urinary self-catheterization. The low-friction hydrophilic surface activates immediately upon exposure to water for fast, clean lubrication and maximum ease of use. To facilitate catheterization, the Self Cath® Plus offers an uncoated GripZone™ area. It is flexible, has smooth fire polished eyelets and is made of medical grade polyvinyl chloride (PVC). The applicant claims that hydrophilic catheters are not functionally equivalent to catheters made with other materials, and provide improved clinical outcomes, and therefore they are fundamentally different from other catheters coded at A4351 and A4352. The applicant also claims that patient access is limited "due to low reimbursement which is a result of current HCPCS categorization"; and suggest that there is a National Medicaid program operating need to isolate hydrophilic catheters from catheters made with other materials.

CMS HCPCS Workgroup Preliminary Decision: To use existing codes A4351 Intermittent urinary catheter, straight tip, with or without coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each or A4352 Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each (as appropriate).

Existing codes A4351 or A4352 (depending on whether the catheter is straight or coude tipped) adequately describe a category of intermittent catheters used to drain the urinary bladder. Chemical, physical, technological and cost differences between catheters made of hydrophilic catheters and catheters made of other materials do not change the primary function of the device, intermittent drainage of the urinary bladder. Clinical information provided does not demonstrate a difference in clinical indications or outcome based on use of catheters made of hydrophilic vs: other materials. No payer representative (Medicare, Medicaid, Private Insurer) of the CMS HCPCS Workgroup identified a national program operating need to alter the existing code set to distinguish catheters make with hydrophilic materials from catheters make with other materials. There are mechanisms within the HCPCS Level II code set that enable flexibility for individual insurers or individual states to isolate hydrophilic catheters for tracking or differential payment if they so choose.

Primary Speaker – John Anderson, of Mentor Corporation, disagreed with the preliminary decision. Mr. Anderson claimed that existing codes do not adequately describe hydrophilic catheters because hydrophilic catheters are technologically, functionally and clinically different than conventional catheters.

He also claimed that there is also a program need to separately categorize hydrophilic catheters. Mr. Anderson reiterated the original coding request.

Meeting Agenda Item #11
June 21, 2005
HCPCS Request #05.140

Background/Discussion:
Randall Carson of Tyco Healthcare Group LP submitted a request to establish a specific code to describe time-released silver coating for the foley catheter, trade name: Dover Silver Foley Catheter™. According to the requester: 1) existing codes do not describe antimicrobial coatings, specifically silver; 2) this is a new science used to reduce the incidence of nosocomial infections; 3) reimbursement under existing codes is inadequate to cover the cost of this product. According to the requester, the Dover catheter is coated with a lubricious (hydrogel material) hydrophilic topcoat containing an inorganic silver ion-releasing polymer. This coating is on the outer and inner catheter surfaces as well as on the balloon. The hydrogel coating acts as a delivery system by utilizing molecular particles to store and release silver ions throughout a 30-day period. The catheter is designed with two lumens; a drainage lumen and an inflation lumen. A round, molded, reinforced silicone tip, finishes the distal end of the catheter. Two drain eyes on opposing sides of the catheter, contiguous with the drain lumen, are located at the tip of the catheter, just distal to the retention balloon. The smooth balloon to shaft transition reduces insertion trauma. This balloon is inflated with sterile water through a syringe activated spring-loaded check valve and serves to retain the catheter in the bladder.

CMS HCPCS Workgroup Preliminary Decision: To use existing codes A4344 (indwelling catheter, foley type, two-way, all silicone, each) and A4346 (indwelling catheter; foley type, three way for continuous irrigation each), as appropriate.

Existing codes A4344 or A4346 adequately describe categories of foley catheters that function similar to the product that is the subject of this request. The FDA has not recognized silver as an antimicrobial. In its marketing approval letter, the FDA explicitly prohibited the manufacturer from making any claims regarding the effectiveness of the inorganic silver ion-releasing polymer to reduce microbial adherence to the device or to reduce urinary tract infections in the patients treated with the device. The CMS HCPCS Workgroup feels that it is inappropriate to differentiate on the basis of a claim prohibited by the FDA.

There was no Primary Speaker for this item.

Meeting Agenda Item #12
June 21, 2005
HCPCS Request #05.144A & B

Background/Discussion:

Request #05.144 A

Randall R. Carson of Tyco Healthcare Group LP has submitted a request to establish a code for enteral feeding pumps which have two separate interfaces functioning on two separate operation systems, Trade Name: Kangaroo® EntriFlush™ Enteral Feeding Pump and Kangaroo® EPump™ Enteral Feeding Pump. According to the requester, these pumps are two-way or dual pumps that can separately provide enteral formula, and hydration. There are two different interfaces on one pump, which allow you to connect two bags at one time and set different infusion parameters for each. The pump mechanisms are rotary peristaltic as existing pumps, however there are separate operating systems that allow you to set separate infusion rates for the formula, and the hydration.

Request #05.144 B

Randall Carson of Tyco Healthcare Group LP has submitted a request to delete existing kit codes B4035 and B4036 and create a new series of codes to separately identify all kit supplies. According to the requestor, the current codes describe and are priced for one set (one bag and one tubing) for standard pumps, and do not describe a pump set required for dual flow pumps. Both of the existing code descriptors state "supply kit; per day" and only one unit of service can be billed for any one day. The requestor is asking for a series specific codes that will describe actual supplies used for enteral feeding, instead of using the terminology "kits". The list of supplies that codes would need to be established for are:

- Piercing spike pump set with 100ml water bag (dual flow set)
- 1000ml bag/pump set with 1000ml water bag (dual flow set)
- "Y" pump set with in line "Y" adaptor and piercing spike
- "Y" pump set with line "Y" adaptor and bag
- Top fill rigid container pump set – 500ml
- Top fill rigid container pump set – 1000ml
- 1000ml anti-free flow pump set
- 500ml anti-free flow pump set
- Screw cap pump set for rigid containers
- Top fill bag pump set – 500ml
- Top fill bag pump set – 1000ml
- Proximal spike pump set
- Pump set tubing extension
- Y-site extension set
- 1000 feed pump set with integrated flush bag
- 1000ml gravity bag
- Large bore gravity set
- Gravity feeding set with piercing pin
- Gravity feeding set with screw-on top

- Re-Certification Pump Set (#776150, ePump only)
- These items would also need duplicate codes for DEHP-free

CMS HCPCS Workgroup Preliminary Decision:
#05.144A
To use existing codes B9000 (enteral nutrition infusion pump-without alarm); or existing code B9002 enteral nutrition infusion pump-without alarm for the pump.

Existing codes B9000 and B9002 adequately describe pumps; with and without an alarm. It is not necessary to have separate lines for nutrition and hydration to be absorbed by the body or to adjust calories and hydration. This is not new technology, and there are no significant therapeutic distinctions between the category of items described by B9002 and the items that are the subject of this request. Appropriate code assignment is made by the insurer in whose jurisdiction a claimis filed. For private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim is being filed. For Medicare, use existing code B9000 or B9002, depending upon whether the pump has an alarm. No insurer indentified a national progam operating need to alter the existing code set to describe this item.

#05.144B
To use existing codes B4035 (enteral feeding supply kit; pump fed, per day) and B4036 (enteral feeding supply kit; gravity fed, per day) for the kit, as appropriate.

Existing kit codes B4035 and B4036 are the mechanism preferred by payers to be used to process a claim for the combination of enteral feeding supplies needed by an individual patient. No insurer identified a national program operating need to alter the existing code set or claims processing mechanism to separately identify and report the specific list of feeding supply items used by individual patients.

Primary Speaker – David R. Thomas, M.D., of St. Louis University Health Services Center on behalf of Tyco, disagreed with the preliminary decision; claims that there are design features and functional differences between enteral feeding and hydration not distinguished in current codes; that separate codes are needed to accumulate date to look at differences; and requests that the CMS HCPCS Workgroup reconsider their preliminary decision and:

- Create a new HCPCS code for “two-way enteral nutrition pump with flushing capability” due to the necessity of flushing and hydration for tube fed patients.
- Change in coding verbiage for B4035 to reflect the hydration/feeding needs for 2 kits (“Enteral Feeding Supply kit, Pump Fed, each”) instead of “per day”.

Meeting Agenda Item #13
June 21, 2005
HCPCS Request #05.184

Background/Discussion:
Daniel McMahon of Viasys Healthcare MedSystems submitted a request to establish a unique code for an enteral gastric pressure relief system, trade name: Farrell Valve. According to the requestor, Farrell Valve is a passive, disposable, closed system designed to provide motility to the gut and relieve severe gastric distension and its attendant decreased lung volume, debilitating pain and reducing the risk of aspiration pneumonia so that sufferers may return to their normal activities of daily living. Farrell Valve is attached to any approved gastric access device and provides a means for air and other gastric contents to escape the stomach into a closed container. The container includes a one-way vent to allow the air to escape the bag while nutrients and medications are returned to the stomach. Farrell Valve is indicated anytime sever gastric distension occurs.

CMS HCPCS Workgroup Preliminary Decision: Use existing B4034(enteral feeding supply kit; syringe, per day), B4035(enteral feeding supply kit; pump fed, per day) or B4036(enteral feeding supply kit; gravity fed, per day) as appropriate, depending upon how the patient is fed.

Existing codes B4034, B4035 and B4036 are indicated for use on a claim to bill for whatever combination of supplies an individual patient requires for enteral feeding, per day. If a patient requires a gastric pressure relief valve, provision of the valve is included under one of these codes, regardless of the particular brand or type of valve used, or whether it is part of an open or a closed system. The Farrell Valve, which has been on the market since it received FDA 510K approval for marketing approximately 20 years ago, is not new technology. It was included in the array on enteral feeding items considered at the time codes B4034, B4035 and B4036 were established and fees associated with the codes were established by payers. No insurer identified a national program operating need to make distinctions between brands and types of individual products used, or even to itemize or count the supplies or the innumerable combinations of supplies that individual patients might need, in order to implement an enteral feeding benefit. There is not a therapeutic distinction between closed system and open system gastric relief valves, in that they are both used for decompression. There is not sufficient evidence to demonstrate that closed system as opposed to open system is necessary for a particular subset of the patients who require enteral feeding. Inquires regarding coding and coverage of gastric relief valves for indications other than enteral feeding should be submitted to the insurer in whose jurisdiction a claim would be filed. The setting of rates and fees is not within the jurisdiction of the code set maintainers. If you have concerns regarding the reimbursement rate associated with codes B4034, B4035 or B4036, please contact the insurer directly. For Medicare, please contact CMS' Inherent Reasonableness Authority. For private insurance systems, please contact the individual insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which a claim would be filed.

Primary Speaker – Daniel J. McMahon of VIASYS MedSystems disagreed with the preliminary decision, claiming that it focuses only on patients who are undergoing enteral feeding, and further claimed the following:

- Only 1/3 of enterally fed patients will benefit from the Farrell Valve.
- There are a variety of medical conditions (16 presented in the application) which:
  - Do not involve enteral feeding.
  - Do cause severe gastric distension.
  - These patient populations benefit from the use of the Farrell Valve.
- Farrell Valve is covered by a number of national private insurers (10 named in the application).
- The current situation represents a gross deficiency in Medicare/Medicaid reimbursement and constitutes a different and diminished standard of care for CMS clients.

VIASYS MedSystems reiterated its request that the CMS HCPCS Workgroup decision be reviewed and changed to provide a HCPCS code for devices, such as the Farrell Valve, that mimic gastric motility, relieve gastric pressure and allow patients to return to their normal activities of daily living.

Meeting Agenda Item #14
June 21, 2005
HCPCS Request #05.141

Background/Discussion:
Celeste Bonham of Uro Concepts Inc. has submitted a request to establish a code for a urine collection bag holder, Trade Name: Better Pant. According to the requestor, this item is an undergarment that holds the urinary collection bag in place on the user's leg without the need of leg straps. This leg bag holder is designed to protect against painful leg ulcers caused from abrasive leg straps against the skin and it will not constrict circulation to the lower leg of the user. It is designed to be used with most urinary collection systems using 500ml or 1000ml bags. It contains an internal pouch that conceals and securely holds the urinary collection bag in place without leg straps.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a code.

This is considered a convenience item not primarily medical in nature. No insurer identified a national program operating need to alter the existing code set to describe this item. Appropriate code assignment is made by the insurer in whose jurisdiction the claim is filed. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. There is no existing Medicare benefit category for the item that is the subject of your request. For Medicare, A9270 is the appropriate code. The use of A4335 and KX modifier for this product is inappropriate. For private sector health insurance systems, please contact the individual private insurance contractor.

There was no Primary Speaker for this item.

Meeting Agenda Item #15
June 21, 2005
HCPCS Request #05.162

Background/Discussion:
Dan Tradden of Cytyc LP has submitted a request to establish a code for an endometrial ablation system, Trade Name: NovaSure™ Catheter, Ablation, Radio Frequency (RF), Impedence Controlled, Endometrial. According to the requestor, this product applies a precisely controlled dose of electrical energy to remove the lining of the uterus, or endometrium, in women diagnosed with excessive menstrual bleeding due to benign causes in pre-menopausal women for whom childbearing is complete. CPT code 58563 HYSTEROSCOPY, SURGICAL; WITH ENDOMETRIAL ABLATION (EG, ENDOMETRIAL RESECTION, ELECTROSURGICAL ABLATION, THERMOABLATION) is currently used to describe this procedure. According to the requester, the RVU's associated with CPT 58563 include the cost of the device when the procedure is performed in a physician's office; the APC payment includes the cost of the device when the procedure is performed in the hospital outpatient department. However, the requester claims that the payment assigned to Group 4 of the Medicare ASC Fee Schedule does not include the cost of the device, and is seeking a code and a means of compensating for the device in an ASC.

CMS HCPCS Workgroup Preliminary Decision: Do not establish a code.

Your request for a code has not been approved. Surgical instruments do not warrant inclusion in the HCPCS Level II code set. Inquiries regarding CPT coding guidance or regarding ablation systems considered during valuation of CPT 58563 should be submitted to the American Medical Association. This item is a component of a procedure and it is not separately payable. For pricing questions, contact individual insurers. For private sector health insurance systems, please contact the individual private insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. For Medicare, this item is included as a component of the procedure performed in OPPS, in an ASC or in a physician's office. Questions regarding payment for Medicare may be submitted to the Director of CMS' Division of Outpatient Care.

There was no Primary Speaker for this item.

Meeting Agenda Item #16
June 21, 2005
HCPCS Request #05.168

Background/Discussion:
Mary St. Pierre of the National Association for Home Care and Hospice has submitted a request to establish a code for social work services in the home, per visit. Social work services visits are provided to individuals in their homes for medically necessary care. Home care providers have traditionally billed and been paid for intermittent social work services care on a per visit basis. Existing codes are available to identify social work services visits in 15 minute increments, by the hour and per diem.

CMS HCPCS Workgroup Preliminary Decision: To use existing code G0155(services of clinical social worker in home health setting, each 15 minutes); or existing code S9127(social work visit, in the home, per diem); or the appropriate CPT code, as instructed by the insurer.

Existing codes G0155 and S9127 adequately describe Social Work Services in the home. Appropriate code assignment and payment increment is made by the insurer in whose jurisdiction the claim is filed. For Medicare, G0155 is the appropriate code. Medicare is adhering to statutory requirement by using 15 minute increments. For private sector health insurance systems, use S9127 or the appropriate CPT code, as instructed by the insurer. Most states adjusted their systems to use 15 minute increments. For appropriate code assignment for Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. No insurer identified a national program operating need to alter the existing code set to describe Social Work Services in per visit increments.

Primary Speaker – (For items 16-20) Mary St. Pierre, of the National Association for Home Care and Hospice, disagrees with the preliminary decisions because "per diem" and "visit" are not comparable, non-Medicare payers are not required to use the 15 minute unit of service, and that S codes and CPT codes do not represent the variety of services provided.

Meeting Agenda Item #17
June 21, 2005
HCPCS Request #05.169

Background/Discussion:
Mary St. Pierre of the National Association for Home Care and Hospice has submitted a request to establish a code for occupational therapy, in the home, per visit. According to the requestor, HCPCS codes are available for reporting home health services in 15 minute increments, as required by Medicare, and hourly and per diem as needed for payers who pay these services in these increments. No codes currently exist for "visits".

CMS HCPCS Workgroup Preliminary Decision: To use existing code G0152 (services of occupational therapist in home health setting, each 15 minutes); or existing code S9129 (occupational therapy, in the home, per diem).

Existing codes G0152 and S9129 adequately describe Occupational Therapy Services in the home. Appropriate code assignment and payment increment is made by the insurer in whose jurisdiction a claim is filed. For Medicare, G0152 is the appropriate code, and services are reported in 15 minute increments. For private sector health insurance systems, use S9129. Most states adjusted their systems to use 15 minute increments. For appropriate code assignment for Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. No insurer identified a national program operating need to alter the existing code set to describe Occupational Therapy Services in "per visit" increments.

Primary Speaker – Same as agenda item #16.

Meeting Agenda Item #18
June 21, 2005
HCPCS Request #05.170

Background/Discussion:
Mary St. Pierre of the National Association for Home Care and Hospice has submitted a request to establish a code for speech language pathology services, in the home, per visit. According to the requestor, HCPCS codes are available for reporting home health services in 15 minute increments, as required by Medicare, and hourly and per diem as needed for payers who pay these services in these increments. No codes currently exist for "visits".

CMS HCPCS Workgroup Preliminary Decision: To use existing code G0153 (services of speech and language pathologist in home health setting, each 15 minutes.

Existing code G0153 adequately describes Speech/Language Pathology Services in the home. Appropriate code assignment is made by the insurer in whose jurisdiction a claim is filed. No insurer identified a national program operating need to alter the existing code set to describe Speech/Language Pathology Services in "per visit" increments. For Medicare, use existing code G0153. For private sector health insurance systems, contact the individual insurance contractor. For Medicaid systems, contact the Medicaid Agency in the state in which a claim is being filed.

Primary Speaker – Same as agenda item #16.

Meeting Agenda Item #19
June 21, 2005
HCPC Request #05.171

Background/Discussion:
Mary St. Pierre of the National Association for Home Care and Hospice has submitted a request to establish a code for "nursing, in the home, per visit." According to the requestor, HCPCS codes are available for reporting home health services in 15 minute increments, as required by Medicare, and hourly and per diem as needed for payers who pay these services in these increments. No codes currently exist for "visits".

CMS HCPCS Workgroup Preliminary Decision: To use existing code G0154 (services of skilled nurse in home health setting, each 15 minutes), or the appropriate CPT code as instructed by the insurer.

Existing code G0154 adequately describes Skilled Nursing Services in the home. Appropriate code assignment is made by the insurer in whose jurisdiction a claim is filed. No insurer identified a national program operating need to describe skilled nursing services in "per visit" increments. For Medicare, use existing code G0154. For private sector health insurance systems, use the appropriate CPT code. For guidance, contact the individual insurance contractor. For Medicaid systems, contact the Medicaid Agency in the state in which a claim is being filed.

Primary Speaker – Same as agenda item #16.

Meeting Agenda Item #20
June 21, 2005
HCPCS Request #05.172

Background/Discussion:
Mary St. Pierre of the National Association for Home Care and Hospice has submitted a request to establish a code for "physical therapy, in the home, per visit". According to the requestor, HCPCS codes are available for reporting home health services in 15 minute increments, as required by Medicare, and hourly and per diem as needed for payers who pay these services in these increments. No codes currently exist for "visits".

CMS HCPCS Workgroup Preliminary Decision: To use existing code G0151 (services of physical therapist in home health setting, each 15 minutes), or S9131 (physical therapy; in the home; per diem).

Existing codes G0151 and S9131 adequately describe Physical Therapy Services in the home. Appropriate code assignment and payment increment is made by the insurer in whose jurisdiction a claim is filed. For Medicare, G0151 is the appropriate code, and services are reported in 15 minute increments. For private sector health insurance systems, use S9131. Most states adjusted their systems to use 15 minute increments. For coding guidance for Medicaid systems, please contact the Medicaid Agency in the state in which a claim is being filed. No insurer identified a national program operating need to alter the existing code set to describe Physical Therapy Services in "per visit" increments.

Primary Speaker – Same as agenda item #16.

Meeting Agenda Item #21
June 21, 2005
HCPCS Request #04.196

Background/Discussion:

Sharon Whalen, of World Heart, Inc., submitted a request to establish 11 codes for a left ventricular assist device, Trade Name: Novacor Left Ventricular Assist System. The Novacor Left Ventricular Assist System assists the damaged or weakened heart in pumping blood to the body. The pump/drive unit, which is the implanted portion of the LVAS, consists of a pump integrated with an energy converter and a single percutaneous lead carrying the control and power wires. The pump drive is implanted into the patient, and restores the patient's hemodynamics and end-organ body flow.

CMS HCPCS Workgroup Preliminary Decision:

Use the following newly established codes as appropriate, depending on the characteristics of your product. These codes will be effective October 1, 2005.

Q0480 DRIVER FOR USE WITH PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0481 MICROPROCESSOR CONTROL UNIT FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0482 MICROPROCESSOR CONTROL UNIT FOR USE WITH ELECTRIC/PNEUMATRIC COMBINATION VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0483 MONITOR/DISPLAY MODULE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0484 MONITOR/DISPLAY MODULE FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0485 MONITOR CONTROL CABLE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0486 MONITOR CONTROL CABLE FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0487 LEADS (PNEUMATIC/ELECTRICAL) FOR USE WITH ANY TYPE ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0488 POWER PACK BASE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0489 POWER PACK BASE FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0490 EMERGENCY POWER SOURCE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0491 EMERGENCY POWER SOURCE FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0492 EMERGENCY POWER SUPPLY CABLE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0493 EMERGENCY POWER SUPPLY CABLE FOR USE WITH ELECTRIC/PNEUMATIC ASSIST DEVICE, REPLACEMENT ONLY

Q0494 EMERGENCY HAND PUMP FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0495 BATTERY/POWER PACK CHARGER FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0496 BATTERY FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0497 BATTERY CLIPS FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0498 HOLSTER FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0499 BELT/VEST FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0500 FILTERS FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0501 SHOWER COVER FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0502 MOBILITY CART FOR PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0503 BATTERY FOR PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY, EACH

Q0504 POWER ADAPTER FOR PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY, VEHICLE TYPE

Q0505 MISCELLANEOUS SUPPLY OR ACCESSORY FOR USE WITH VENTRICULAR ASSIST DEVICE

There was no Primary Speaker for this item.

Meeting Agenda Item #22
June 21, 2005
HCPCS Request #04.197

Background/Discussion:

Robin Bostic, of the Thoratec Corporation, has submitted a request to establish 7 codes for a ventricular assist device and related prosthetic devices, Trade Name: Thoratec TLC-II Portable VAD Driver and related prosthetic devices. The device is used for partial circulatory assistance or for total support of the right and/or left ventricles. The TLC driver is a lightweight, portable, pneumatic VAD driver, powered by batteries or from external power. It is designed to provide portable pneumatic drive power for ambulatory VAD patients. Left ventricular assist devices are used to assist a damaged or weakened heart in pumping blood. The VAD prosthetic devices needed to for necessary outpatient use include the VAD driver, rechargeable batteries, a car power adapter, and a mobility cart. As a result of the shift to the home-care/out-of-hospital use of VAD's for destination therapy, it is necessary to establish codes for the components necessary for home use. VAD components also need replacement over time.

CMS HCPCS Workgroup Preliminary Decision:

Use the following newly established codes as appropriate, depending on the characteristics of your product. These codes will be effective October 1, 2005.

Q0480 DRIVER FOR USE WITH PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0481 MICROPROCESSOR CONTROL UNIT FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0482 MICROPROCESSOR CONTROL UNIT FOR USE WITH ELECTRIC/PNEUMATRIC COMBINATION VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0483 MONITOR/DISPLAY MODULE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0484 MONITOR/DISPLAY MODULE FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0485 MONITOR CONTROL CABLE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0486 MONITOR CONTROL CABLE FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0487 LEADS (PNEUMATIC/ELECTRICAL) FOR USE WITH ANY TYPE ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0488 POWER PACK BASE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0489 POWER PACK BASE FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0490 EMERGENCY POWER SOURCE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0491 EMERGENCY POWER SOURCE FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0492 EMERGENCY POWER SUPPLY CABLE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0493 EMERGENCY POWER SUPPLY CABLE FOR USE WITH ELECTRIC/PNEUMATIC ASSIST DEVICE, REPLACEMENT ONLY

Q0494 EMERGENCY HAND PUMP FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0495 BATTERY/POWER PACK CHARGER FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0496 BATTERY FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0497 BATTERY CLIPS FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0498 HOLSTER FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0499 BELT/VEST FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0500 FILTERS FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0501 SHOWER COVER FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0502 MOBILITY CART FOR PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0503 BATTERY FOR PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY, EACH

Q0504 POWER ADAPTER FOR PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY, VEHICLE TYPE

Q0505 MISCELLANEOUS SUPPLY OR ACCESSORY FOR USE WITH VENTRICULAR ASSIST DEVICE

There was no Primary Speaker for this item.

Meeting Agenda Item #23
June 21, 2005
HCPCS Request #04.198

Background/Discussion:
Robin Bostic, of the Thoratec Corporation, has submitted a request to establish 13 codes for a ventricular assist device products for home use, Trade Name: Heart Mate® Implantable, pulsatile, ventricular assist device (VAD) products for home use. A series of codes are being requested to describe the products used in conjunction with the ventricular assist device, including the system controller, display module, battery set, vent filters, emergency power pack, emergency hand pump, vent adapter, module battery, battery holster, battery clip set, VAD stabilization belt, and VAD shower kit. Implantable, pulsatile, ventricular assist devices are pump-type devices that are surgically implanted to augment the hearts pumping ability and provide long-term circulatory support for patients with heart failure who are heart transplant candidates and patients requiring the VAD for destination therapy. The VAD consists of tubing that draws blood away from the affected ventricles and into a mechanical pulsatile pump that is implanted in the patient's chest. The LVAD is capable of producing a stroke volume of 83ml, generating approximately 10 liters of blood flow per minute and a heart beat rate up to 120 beats per minute. The electric motor is connected to the external system controller and external power components via a percutaneous tube. As a result of the shift to the home-care/out-of-hospital use of VAD's for destination therapy, it is necessary to establish codes for the components necessary for home use. VAD components also need replacement over time.

CMS HCPCS Workgroup Preliminary Decision:

Use the following newly established codes as appropriate, depending on the characteristics of your product. These codes will be effective October 1, 2005.

Q0480 DRIVER FOR USE WITH PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0481 MICROPROCESSOR CONTROL UNIT FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0482 MICROPROCESSOR CONTROL UNIT FOR USE WITH ELECTRIC/PNEUMATRIC COMBINATION VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0483 MONITOR/DISPLAY MODULE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0484 MONITOR/DISPLAY MODULE FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0485 MONITOR CONTROL CABLE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0486 MONITOR CONTROL CABLE FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0487 LEADS (PNEUMATIC/ELECTRICAL) FOR USE WITH ANY TYPE ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0488 POWER PACK BASE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0489 POWER PACK BASE FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0490 EMERGENCY POWER SOURCE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0491 EMERGENCY POWER SOURCE FOR USE WITH ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0492 EMERGENCY POWER SUPPLY CABLE FOR USE WITH ELECTRIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0493 EMERGENCY POWER SUPPLY CABLE FOR USE WITH ELECTRIC/PNEUMATIC ASSIST DEVICE, REPLACEMENT ONLY

Q0494 EMERGENCY HAND PUMP FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0495 BATTERY/POWER PACK CHARGER FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0496 BATTERY FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0497 BATTERY CLIPS FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0498 HOLSTER FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0499 BELT/VEST FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0500 FILTERS FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0501 SHOWER COVER FOR USE WITH ELECTRIC OR ELECTRIC/PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0502 MOBILITY CART FOR PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY

Q0503 BATTERY FOR PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY, EACH

Q0504 POWER ADAPTER FOR PNEUMATIC VENTRICULAR ASSIST DEVICE, REPLACEMENT ONLY, VEHICLE TYPE

Q0505 MISCELLANEOUS SUPPLY OR ACCESSORY FOR USE WITH VENTRICULAR ASSIST DEVICE

There was no Primary Speaker for this item.

Closing Remarks

In light of new information provided at CMS' HCPCS Public Meetings, the HCPCS workgroup will reconsider its preliminary coding recommendations, CMS staff will reconsider payment methodology recommendations, and the workgroup will formulate its final recommendation. By mid November 2005, the HCPCS workgroup will mail letters to every requestor of its final decision. The 2006 HCPCS Level II Annual Update, including any coding changes, will be effective January 1, 2006, and will be published at: www.cms.hhs.gov/providers/pufdownload/anhcpcdl.asp by mid November, 2005.

Cindy Hake of CMS thanked the participants for their very valuable input at the meeting, and for all the time and effort that was spent on the presentations.

Robin Williams also thanked the audience for their participation, and officially adjourned the meeting.