Centers for Medicare & Medicaid Services (CMS)
Summary Report
HCPCS Public Meeting
Wednesday, June7, 2006

Introduction and Overview

Denise Bailey-Jones, CMS Office of Operations Management, moderated the meeting. Approximately 30 people attended. The agenda included 17 items.

CMM staff 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. The 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://www.cms.hhs.gov/DMEPOSFeeSched/LSDMEPOSFEE/list.asp?filterType=none&filterByDID=0&sortByDID=3&sortOrder=descending.

Cindy Hake provided an overview of the HCPCS public meeting process and the overall HCPCS process.

Prior to Public Meetings, the CMS HCPCS workgroup meets to review the coding requests on the public meeting agenda, and to make a preliminary coding recommendations. CMS also makes 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 HCPCS world-wide web site at www.cms.hhs.gov/medhcpcsgeninfo, as part of the HCPCS public meeting agendas.

Following the public meeting, the CMS HCPCS workgroup will use the input provided at the Public Meeting to reconsider its preliminary coding recommendations, and CMS staff will reconsider its pricing recommendations. The CMS HCPCS workgroup is the entity that 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.

Public Meetings are not CMS HCPCS workgroup meetings. Final decisions are not made at the public meetings. All requestors will be notified in writing, in November, of the 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 are posted on the official HCPCS world wide web site at: http://cms.hhs.gov/medhcpcsgeninfo in a document entitled: "Alpha-Numeric HCPCS Coding Recommendation Format. The standard application

format 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.

HCPCS Meeting Agenda Item #1
June 7, 2006
Request #06.104

Topic/Issue:

Request to 1) Establish 3 new codes for hydrophilic single use intermittent urinary catheters, Trade Names: LoFric®, LoFric® Plus, LoFric® Cath-Kit™, LoFric® Ready-Kit, and LoFric® H20 (collectively, LoFric® Catheters(s)) and revise 3 existing codes A4351, A4352 and A4353; 2) revise existing code A4351 and A4352 to omit the word "hydrophilic" from the descriptor; and 3) revise existing code A4353 to add the word "conventional" to the descriptor. Requester Suggested Language for new codes:
AXXXX "Intermittent urinary catheter; straight tip, hydrophilic"
AXXXX "Intermittent urinary catheter; coude (curved) tip, hydrophilic"
AXXXX "Intermittent urinary catheter, hydrophilic, with insertion supplies"
Requester Recommendation for revisions:
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"

Background/Discussion:

According to the requester, the LoFric® Catheter employs a multi-layer construction. A LoFric® Catheter has a core of medical-grade polyvinyl chloride (PVC) (or, in the case of LoFric® Plus, a polyethene-butylacrulate (PEBA) core) 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. Since all hydrophilic catheters achieve their slipperiness through chemical binding of water instead of application of a gel, these catheters – unlike conventional catheters – remain slippery throughout the entire process of insertion, drainage, and removal. However, these same physical properties of hydrophilic catheters prevent their safe reuse. LoFric® Catheters are only slippery when the osmolality of the water bound to the PVP/NaC1 layer is similar to that of urinary tract tissues. Since the osmolality of the water bound to dried and rewet LoFric® Catheters does not match that of urethral tissues, this difference in osmolality draws water from the tissues towards the catheter or vice versa, which can cause the catheter to adhere to the urinary tract tissue. Other brands of hydrophilic catheters also cannot be safely reused. According to the applicant, "hydrophilic catheters are appropriate for use in all patients who require intermittent catheterization."

CMS HCPCS Workgroup Preliminary Decision:

Existing codes **A4351** "INTERMITTENT URINARY CATHETER; STRAIGHT TIP, WITH OR WITHOUT COATING (TEFLON, SILICONE, SILICONE ELASTOMER, OR HYDROPHILIC, ETC.), EACH" and **A4352** "INTERMITTENT URINARY CATHETER; COUDE (CURVED) TIP, WITH OR WITHOUT COATING (TEFLON, SILICONE, SILICONE ELASTOMERIC, OR HYDROPHILIC, ETC.), EACH" adequately describe hydrophilic intermittent catheters used to drain the urinary bladder.

Studies submitted with the 2006 application and studies submitted with prior applications do not demonstrate superior clinical outcomes as a result of using hydrophilic catheters, compared to non-hydrophilic catheters.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to these products.
Pricing = 37

Primary Speaker:
On behalf of Arnold & Porter, LLC, the primary speaker disagreed with the Workgroup's preliminary decision to use existing codes to describe hydrophilic catheters. The speaker claimed that even though the clinical studies that have been done are small, they demonstrate that the use of hydrophilic catheters results in "superior clinical outcomes, for instance, urinary tract infection, hematuria, pain, strictures and inflammation". The speaker noted however, that "conventional catheters demonstrate superior clinical outcomes over hydrophilic catheters if both were to be reused," and "because of these differences in clinical outcomes, separate codes should be established for hydrophilic and conventional catheters". The speaker claimed that hydrophilic catheters "are appropriate for different indications; they are constructed from different materials; they have different instructions for use; … cannot be safely reused; and Medicaid programs… have applied to CMS for unique codes…" The speaker also claimed that "price differences deny access to hydrophilic catheters when lumped into the same code with conventional catheters."

HCPCS Meeting Agenda Item #2
June 7, 2006
Request #06.150

Topic/Issue:
Request for reconsideration of code assignment from *A620*9 "Foam dressing, wound cover, pad size 16 sq. in. or less, without adhesive border, each dressing", *A6210* "Foam dressing wound cover, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing" and *A6211* "Foam dressing, wound cover, pad size more than 48 sq. in., without adhesive border, each dressing" to A6200 "Composite dressing, pad size 16 sq. in. or less, without adhesive border, each dressing", A6201 "Composite dressing, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each" and A6202 "Composite dressing, pad size more than 48 sq. in., without adhesive border, each dressing".

Background/Discussion:
According to the applicant, the dressings that are the subject of this request are currently assigned to HCPCS codes A6209, A6210 and A6211. These codes describe foam dressings. However, the applicants' dressing is a composite of three materials. Alternate codes A6200, A6201 and A6202 better describe composite dressings. Against the wound is a small pore absorptive foam that contains nanocrystallized silver. This layer has been shown to be antimicrobial for up to seven days. The next 2 layers are comprised of larger pore medical grade foam that facilitates wound drainage to be wicked away from the wound. The most outside layer is made of sterile cloth flocking that allows the bandage to be adhered to the wound site via Velcro straps, or plain roller gauze. Due to the thickness of the dressing, an increase in skin temperature has been detected in the immediate area of the wound. This allows an increase of blood flow to the area to encourage expedited wound healing. The product comes sterile (gamma-irradiated), with no need for special storage conditions. The dressing is removed from the package and applied directly to the wound. Again, depending on the amount drainage, the dressing can be left in place for up to seven days. Due to the ease of application, the patient can apply the dressing at home effortlessly. This Multi-Density Polyurethane Foam Wound Dressing System is primarily used as an ulcer/surgical/burn wound dressing. The dressing is to be applied (silver side down) directly to an open ulcer/burn surgical wound to keep the wound bed bacterial free, sterile, and moist, to facilitate closure.

CMS HCPCS Workgroup Preliminary Decision:
This product does not meet criteria for classification as a composite dressing. Continue to use existing code **A6209** "FOAM DRESSING, WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING",

A6210 "FOAM DRESSING, WOUND COVER, PAD SIZE MORE THAN 16 SQ. IN., BUT LESS THAN OR EQUAL TO 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING" or **A6211** "FOAM DRESSING, WOUND COVER, PAD SIZE MORE THAN 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING", as appropriate depending on size.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to these products.
Pricing = 35

Primary Speaker:
On behalf of Dr. Lens Medical Products, the primary speaker respectfully requested that the codes for Dr. Lens medical products be changed from foam dressing codes to composite dressing codes. According to the speaker, the dressings are made of at least 3 distinct materials, including a layer of nanocrystallized impregnated polyurethane foam, two layers of medical grade foam, and a layer of cotton flocking, and therefore should be considered composite dressings and coded as such.

HCPCS Meeting Agenda Item #3
June 7, 2006
Request #06.99

Topic/Issue:
Request to establish 3 codes for silver coated dressing, trade name: ACTICOAT Moisture Control Antimicrobial Barrier Dressing based on pad size. Requester Suggested Language**:**
AXXXX "Antimicrobial Bactericidal Foam Barrier Dressing, wound cover, pad size 16 sq in or less, without an adhesive border, each dressing"
AXXXX "Antimicrobial Bactericidal Foam Barrier Dressing, wound cover, pad size more than 16 sq in but less than or equal to 48 sq in, without an adhesive border, each dressing"
AXXXX "Antimicrobial Bactericidal Foam Barrier Dressing, wound cover, pad size more than 48 sq in, without an adhesive border, each dressing"

Background/Discussion:
According to the requester, ACTICOAT Moisture Control is an effective barrier to bacterial penetration into acute/chronic partial and full thickness wounds. ACTICOAT Moisture Control consists of a nanocrystalline silver coated polyurethane layer, a polyurethane foam layer and blue waterproof polyurethane film layer providing an effective barrier to bacterial penetration.

ACTICOAT is the only dressing currently on the market that provides a sustained release of bactericidal [kills bacteria] levels of silver which the requester claims reduces the frequency of dressing changes contributing to a reduction in nursing time and wound infection. Studies have consistently shown that less frequent dressing changes are cost effective and reduce the risk of infection. Frequent removal of dressings colonized with bacteria releases appreciable numbers of organisms into the air despite careful aseptic techniques. Frequent dressing changes increases the potential for nosocomial infections, increase cost of care and complications, increase pain, disrupt newly formed epithelial cells and delay healing. According to the requester, existing codes A6209 "FOAM DRESSING, WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING" and A6210 "FOAM DRESSING, WOUND COVER, PAD SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING", as verified by the SADMERC, do not describe the antimicrobial barrier elements of ACTICOAT dressings, and also do not describe pad sizes larger than 48 sq. in.

CMS HCPCS Workgroup Preliminary Decision:
Existing code **A6209** "FOAM DRESSING, WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING"; **A6210** "FOAM DRESSING, WOUND COVER, PAD SIZE MORE THAN 16 SQ. IN., BUT LESS THAN OR EQUAL TO 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING"; or **A6211** "FOAM DRESSING, WOUND COVER, PAD SIZE MORE THAN 48 SQ. IN., WITHOUT ADHESIVE BORDER, EACH DRESSING", (depending on size) adequately describes the products that are the subject of this application. Clinical information provided by applicant does not support a claim of

superior clinical outcome when this product is used, when compared with other products coded at A6209-A6211.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to these products.
Pricing = 35

Primary Speaker:
On behalf of Smith and Nephew, the primary speaker disagreed with the workgroup's preliminary decision. The speaker claims that Acticoat barrier dressings offer additional benefits, including the prevention and reduction of current and recurrent wound infections, that alginate and foam dressings do not. According to the speaker, the preliminary decision does not recognize the structural component of antimicrobial dressings, or their additional clinical benefits: bactericidal and bacteriostatic, and because of the demonstrated additional benefits, these products should be assigned codes outside of the current traditional categories of alginate, collagen, and foam dressings.

HCPCS Meeting Agenda Item #4
June 7, 2006
Request #06.100

Topic/Issue:
Request to establish 3 codes for silver coated dressing, trade name: ACTICOAT Absorbent Antimicrobial Barrier Dressing based on pad size.
Requester Suggested Language**:**
AXXXX "Antimicrobial Bactericidal Alginate Barrier Dressing, wound cover, pad size 16 sq in or less, without an adhesive border, each dressing"
AXXXX "Antimicrobial Bactericidal Alginate Barrier Dressing, wound cover, pad size more than 16 sq in but less than or equal to 48 sq in, without an adhesive border, each dressing"
AXXXX "Antimicrobial Bactericidal Alginate Barrier Dressing, wound cover, pad size more than 48 sq in, without an adhesive border, each dressing"

Background/Discussion:
According to the requester, ACTICOAT Absorbent is a silver-coated barrier dressing utilized in the topical treatment of acute and chronic partial- and full-thickness wounds to prevent and minimize the introduction and proliferation of bacteria to the wound surface.

To be bactericidal [kills bacteria], silver must be available in ionic form which occurs when silver is exposed to moisture. ACTICOAT Absorbent is the only bactericidal dressing currently on the market with an adequate level [70 – 100 parts per million [ppm]] for a period of up to three days. The literature supports that this level is more beneficial than lower levels. The efficacy is dependent on the concentration of silver ions present. Silver ions are toxic to bacteria because they bind DNA and disrupt cell reproduction, bacterial respiration enzyme systems, and bacterial cell wall integrity.

ACTICOAT is the only dressing currently on the market that provides a sustained release of bactericidal [kills bacteria] levels of silver which the requester claims reduces the frequency of dressing changes contributing to a reduction in nursing time and wound infection. Studies have consistently shown that less frequent dressing changes are cost effective and reduce the risk of infection. Frequent removal of dressings colonized with bacteria releases appreciable numbers of organisms into the air despite careful aseptic techniques. Frequent dressing changes increases the potential for nosocomial infections, increase cost of care and complications, increase pain, disrupt newly formed epithelial cells and delay healing. According to the requester, existing codes A6199 "ALGINATE OR OTHER FIBER GELLING DRESSING, WOUND FILLER, PER 6 INCHES" and A6197 "ALGINATE OR OTHER FIBER GELLING DRESSING, WOUND COER, PAD SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH DRESSING", as verified by the SADMERC, do not describe the antimicrobial barrier elements of ACTICOAT dressings, and also do not describe pad sizes larger than 48 sq. in.

CMS HCPCS Workgroup Preliminary Decision:
Existing code: **A6196** "ALGINATE OR OTHER FIBER GELLING DRESSING WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, EACH DRESSING"; **A6197** "ALGINATE OR OTHER FIBER GELLING DRESSING, WOUND COVER, PAD SIZE MORE THAN 16 SQ.IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH DRESSING"; or **A6199** "ALGINATE OR OTHER FIBER GELLING DRESSING, WOUND FILLER, PER 6 INCHES", (based on product characteristics and size) adequately describes the products that are the subject of this request. Clinical information provided by applicant does not support a claim of superior clinical outcome when this product is used, when compared with other products coded at A6196, A6197 and A6199.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to these products. Pricing = 35

Primary Speaker:
On behalf of Smith and Nephew, the primary speaker disagreed with the workgroup's preliminary decision. The speaker claims that Acticoat barrier dressings offer additional benefits, including the prevention and reduction of current and recurrent wound infections, that alginate and foam dressings do not. According to the speaker, the preliminary decision does not recognize the structural component of antimicrobial dressings, or their additional clinical benefits: bactericidal and bacteriostatic, and because of the demonstrated additional benefits, these products should be assigned codes outside of the current traditional categories of alginate, collagen, and foam dressings.

HCPCS Meeting Agenda Item #5
June 7, 2006
Request #06.148

Topic/Issue:
Request to establish 3 codes for antimicrobial barrier dressings, trade name: Acticoat.
Applicants' Recommended language:
AXXXX – Antimicrobial Bactericidal Multi-layer Barrier Dressing, wound cover, pad size 16 sq in or less, without an adhesive border, each dressing.
AXXXX – Antimicrobial Bactericidal Multi-layer Barrier Dressing, wound cover, pad size more than 16 sq in but less than or equal to 48 sq in, without an adhesive border, each dressing.
AXXXX – Antimicrobial Bactericidal Multi-layer Dressing, wound cover, pad size more than 48 sq in, without an adhesive border, each dressing.

Background/Discussion:
According to the requester, ACTICOAT 3/Burn/7 are effective barriers to bacterial penetration into an acute / chronic partial and full thickness wounds. ACTICOAT 3/Burn/7 consists of multilayers: a rayon/polyester inner core sandwiched between outer layers of silver-coated, non-adherent, polyethylene mesh. The sustained release of broad-spectrum ionic silver actively protects the wound site from bacterial contamination, while the inner core maintains the moist environment for optimal wound healing. The barrier function of ACTICOAT 3/Burn/7 reduce infection in acute/chronic partial and full thickness wounds, including pressure, ulcers, venous leg ulcers, diabetic ulcers, surgical wounds, first and second degree burns, and donor and recipient graft site. ACTICOAT 3/Burn/7 are individually packaged in peelable pouches.

CMS HCPCS Workgroup Preliminary Decision:
Existing codes: **A6206** "CONTACT LAYER, 16 SQ. IN. OR LESS, EACH DRESSING", **A6207** "CONTACT LAYER, MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 S1. IN., EACH DRESSING" and **A6208** "CONTACT LAYER, MORE THAN 48 SQ. IN., EACH DRESSING", (depending on size) adequately describe this product. Clinical information provided does not support applicants claim of reduced infection or demonstrate superior patient clinical outcome as a result of use of Acticoat when compared with other products coded at A6206, A6207 and A6208. Use existing codes A6206, A6207 or A6208, depending on size.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to these products.
Pricing = 35

Primary Speaker:
On behalf of Smith and Nephew, the primary speaker disagreed with the workgroup's preliminary decision. The speaker claims that Acticoat barrier dressings offer additional benefits, including the prevention and reduction of current and recurrent wound infections, that alginate and foam dressings do not. According to the speaker, the preliminary decision does not recognize the structural component of antimicrobial dressings, or their additional clinical benefits: bactericidal and bacteriostatic, and because

of the demonstrated additional benefits, these products should be assigned codes outside of the current traditional categories of alginate, collagen, and foam dressings.

HCPCS Meeting Agenda Item #6
June 7, 2006
Request #06.145

Topic/Issue:
Request to establish a code for antimicrobial foam surgical dressing, trade name: Biopatch.

Background/Discussion:
According to the requester, Biopatch is an absorptive hydrophilic polyurethane foam impregnated with chlorhexidine gluconate (CHG). Biopatch continually releases CHG for seven days. The foam material absorbs up to eight times its own weight in fluid while the CHG incorporated into the dressing inhibits bacterial growth under the dressing. Biopatch is a primary dressing that fits around the percutaneous device at the insertion site and is used in combination with either a semi-occlusive or non-occlusive secondary dressing. In the presence of exudates, the Biopatch absorbs exudates and blood, and releases CHG to the surrounding skin. Biopatch acts as a barrier to microorganisms to protect the wound from environmental contamination and minimizes cross-contamination from the wound to the environment. It effectively kills a wide range of microorganisms (including antibiotic-resistant strains) which are commonly found on the skin and in colonized and infected wounds. The product comes in ¾ inch and 1 inch sizes. The applicant suggests code language: "Antimicrobial foam dressing < 16 sq inches."

CMS HCPCS Workgroup Preliminary Decision:
Existing code A6209 "FOAM DRESSING, WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING" adequately describes foam dressings. The applicant did not submit clinical studies to demonstrate superior patient clinical outcome as a result of use of Biopatch, when compared with other products coded in the A6209 category.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to these products. Pricing = 35

Primary Speaker:
On behalf of Johnson & Johnson, the primary speaker disagreed with the preliminary decision regarding the Biopatch Antimicrobial Dressing. The speaker stated that the establishment of previously issued codes is not based on clinical superiority, but rather on product differences. The speaker claimed that the technological differences (components, materials, structural features) in these products warrant a unique code, including the incorporation of antimicrobial and antiseptic agents. According to the speaker, these products reduce proliferation in the dressing or at the wound contact surface; that clinical literature and the FDA support the topical use of silver as an antimicrobial and the use of Chlorhexidine gluconate as effective skin antiseptic and antimicrobial. The speaker also discussed the price of manufacturing dressings that contain antimicrobial agents. And finally, the speaker suggested 6 new codes to identify antimicrobial foam, collagen and alginate dressing products.

HCPCS Meeting Agenda Item #7
June 7, 2006
Request #06.146

Topic/Issue:
Request to establish three codes for antimicrobial alginate surgical dressing, trade name: Silvercel. Requester suggested language**:** 1) AXXXX "Antimicrobial alginate dressing < 16 sq inches", 2) AXXXX "Antimicrobial alginate dressing > 16 sq inches, < 48 sq inches", and 3) AXXXX "Antimicrobial alginate dressing, rope per 6 inches".

Background/Discussion:
According to the requester, Silvercel is a sterile, non-woven pad composed of high G (guluronic acid) alginate, carboxymethlycellulose (CMC) and silver coated nylon fibers. Silvercel also contains elemental silver (8%) in a sustained release formulation. The function of Silvercel is two-fold. It combines the potent broad-specrum antimicrobial action of silver with the enhanced exudates management properties of an alginate dressing. Silver is a proven antimicrobial for controlling bacteria, mold, fungus, algae and yeast. Due to its antimicrobial properties, the dressing functions as a barrier to protect the wound from environmental contamination. By reducing bacterial bioburden, cross-contamination from the wound to the environment may be reduced. When activated by moisture, Silvercel provides an antimicrobial effect to protect the dressing from bacterial contamination for up to 7 days. Silvercel effectively kills a wide range of microorganisms in wounds with bacterial bioburden.

CMS HCPCS Workgroup Preliminary Decision:
Existing codes **A6196** "ALGINATE OR OTHER FIBER GELLING DRESSING WOUND COVER, PAD SIZE 16 SQ. IN. OR LESS, EACH DRESSING", **A6197** "ALGINATE OR OTHER FIBER GELLING DRESSING, WOUND COVER, PAD SIZE MORE THAN 16 SQ.IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH DRESSING", and **A6199** "ALGINATE OR OTHER FIBER GELLING DRESSING, WOUND FILLER, PER 6 INCHES" adequately describe alginate dressings. Clinical information included with the application does not substantiate a claim of reduction in wound infection. Studies were not provided to demonstrate superior patient clinical outcome as a result of using Silvercel dressings when compared with other dressings coded at A6196, A6197 or A6199. Use existing codes A6196, A6197 or A6199, as appropriate based on product characteristics and size.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to these products. Pricing = 35

Primary Speaker:
On behalf of Johnson & Johnson, the primary speaker disagreed with the preliminary decision regarding the Biopatch Antimicrobial Dressing. The speaker stated that the establishment of previously issued codes is not based on clinical superiority, but rather on product differences. The speaker claimed that the technological differences (components, materials, structural features) in these products warrant a unique code, including the incorporation of antimicrobial and antiseptic agents. According to the speaker, these

products reduce proliferation in the dressing or at the wound contact surface; that clinical literature and the FDA support the topical use of silver as an antimicrobial and the use of Chlorhexidine gluconate as effective skin antiseptic and antimicrobial. The speaker also discussed the price of manufacturing dressings that contain antimicrobial agents. And finally, the speaker suggested 6 new codes to identify antimicrobial foam, collagen and alginate dressing products.

HCPCS Meeting Agenda Item #8
June 7, 2006
Request #06.147

Topic/Issue:
Request to establish two codes for antimicrobial collagen dressing, trade name: Prisma Matrix.

Background/Discussion:
According to the requester, Prisma is an advanced wound care device comprised of a sterile, freeze dried dressing composed of 55% collagen, 44% oxidized regenerated cellulose (ORC) and 1% silver-ORC. The function of Prisma is two-fold. It provides protection and facilitates growth. Prisma combines the potent broad-spectrum antimicrobial action of silver with the structural matrix of collagen. In the presence of wound exudates, Prisma transforms into a soft, conformable, biodegradable gel, and thus allows contact with all areas of the wound. Due to its antibacterial properties, the dressing functions as a barrier to protect the wound from environmental contamination. By reducing bacterial bioburden this may reduce cross-contamination from the wound to the environment. The collagen component within Prisma creates an environment that is conducive to granulation tissue formation and epithelialization. Prisma effectively kills a wide range of microorganisms commonly found in colonized and infected wounds which delay wound healing. Applicant suggests code language: 1) AXXXX "Antimicrobial collagen dressing < 16 sq inches"; and 2) AXXXX "Antimicrobial collagen dressing > 16 sq inches, < 48 sq inches".

CMS HCPCS Workgroup Preliminary Decision:
Existing codes **A6021** "COLLAGEN DRESSING, PAD SIZE 16 SQ. IN. OR LESS, EACH", **A6022** "COLLAGEN DRESSING, PAD SIZE MORE THAN 16 SQ. IN. BUT LESS THAN OR EQUAL TO 48 SQ. IN., EACH" and **A6023** "COLLAGEN DRESSING, PAD SIZE MORE THAN 48 SQ. IN., EACH", adequately describe collagen dressings. Studies were not provided with the application to demonstrate superior patient clinical outcome as a result of using Prisma Matrix, when compared with other products in the A6021, A6022 and A6023 code categories. Use existing codes A6021, A6022 or A6023 as appropriate, depending on the size of the pad.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to these products. Pricing = 35

Primary Speaker:
On behalf of Johnson & Johnson, the primary speaker disagreed with the preliminary decision regarding the Biopatch Antimicrobial Dressing. The speaker stated that the establishment of previously issued codes is not based on clinical superiority, but rather on product differences. The speaker claimed that the technological differences (components, materials, structural features) in these products warrant a unique code, including the incorporation of antimicrobial and antiseptic agents. According to the speaker, these products reduce proliferation in the dressing or at the wound contact surface; that clinical literature and the FDA support the topical use of silver as an antimicrobial and the use of

Chlorhexidine gluconate as effective skin antiseptic and antimicrobial. The speaker also discussed the price of manufacturing dressings that contain antimicrobial agents. And finally, the speaker suggested 6 new codes to identify antimicrobial foam, collagen and alginate dressing products.

HCPCS Meeting Agenda Item #9
June 7, 2006
Request #06.120

Topic/Issue:
Request to establish a new code for a contraceptive tubal occlusion device and delivery system, trade name: Essure® System. Requester suggested language: LXXXX "Micro-inserts for bilateral fallopian tube occlusion".

Background/Discussion:
According to the requester, Essure® micro-insert is an implantable device that allows for bilateral fallopian tube occlusion and permanent female sterilization. In contrast to the more invasive surgical procedure of tubal ligation, the Essure implant procedure is a minimally invasive alternative for women who desire permanent birth control. During the Essure implant procedure micro-inserts hysteroscopically placed in the proximal section of each fallopian tube. The micro-inserts elicit a benign tissue response, and occlude the fallopian tube, resulting in permanent sterilization. Once deployed, the spring-like Essure micro-insert expands to conform to the fallopian tube. The spring-like mechanism is intended to provide the necessary anchoring forces during the acute phase of device implantation (3 months post-micro-insert placement). The PET fiber mesh and the micro-insert act as scaffolding into which the tissue grows, anchoring the micro-insert within the fallopian tube and occluding the tube, resulting in sterilization. Recommended language is "micro-inserts for bilateral fallopian tube occlusion".

According to the requester, commercial and government insurers are identifying Essure using new CPT code 58565 (eff. 1/2005) "Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants". However, those insurers who cannot administer a site of service differential are manually processing claims using unlisted HCPCS codes L8699 "PROSTHETIC IMPLANT, NOT OTHERWISE SPECIFIED; E1399 'DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS; or A4649 'SURGICAL SUPPLY; MISCELLANEOUS".

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this product. It is included as part of the practice expense and is not separately payable. Use of miscellaneous codes is inappropriate.

Primary Speaker:
On behalf of Argenta Reimbursement, the primary speaker respectfully disagreed with the preliminary decision. According to the speaker, "practice expense RVU's are appropriate, however many commercial payers and Medicaid agencies cannot reimburse differing amounts based on facility setting. This results in the payers paying for the device twice" in the hospital outpatient setting. The speaker also stated that Level II HCPCS "codes do exist for numerous procedures where the CPT codes have office-based practice expense that includes the cost of the device". The speaker requested that Essure be categorized as a prosthetic implantable device and be granted an L code.

HCPCS Meeting Agenda Item #10
June7, 2006
Request #06.103

Topic/Issue:
Request to establish a code for a complexed prostate specific antigen assay, trade name: Bayer Immuno 1™ Complexed PSA Assay, Bayer ADVIA Centaur® Complexed PSA Assay, Bayer ACS-180® Complexed PSA Assay. Requester suggested language**:** "Prostate cancer screening, prostate specific antigen test, complexed"

Background/Discussion:
According to the requester, subsequent to the creation of code G0103 "PROSTATE CANCER SCREENING; PROSTATE SPECIFIC ANTIGEN TEST (PSA), TOTAL", the FDA approved a test for measuring cPSA, and found a similar predictive value for cPSA compared with total PSA. In 2001, the AMA created a CPT code for reporting cPSA tests, and CMS included the code in its clinical laboratory fee schedule, with payment set at the same rate as that for total PSA tests. In addition, the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for Prostate Cancer Early Detection state that direct measurement of complexed PSA has been found to be equivalent to total PSA in detecting prostate cancer, and that cPSA can be used in place of total PSA in screening for prostate cancer.

Although a CPT code already exists for cPSA, a new code is needed for reporting its use as a screening test because the current HCPCS code for screening PSA tests refers only to total PSA. A new code will give physicians the option of choosing the PSA test they feel is most appropriate for their patients.

CMS HCPCS Workgroup Preliminary Decision:
HCPCS Level II is not the appropriate coding jurisdiction for this item. CMS suggests that the applicant contact the American Medical Association (AMA) CPT Editorial Panel for CPT coding guidance, and consider getting on CMS' list-serve for CMS Lab Open-Door Meetings.

Primary Speaker:
On behalf of Bayer Healthcare, the primary speaker reiterated the request for a HCPCS Level II code, stating that "it is necessary to report the performance of this test as a prostate cancer screening test, because the existing HCPCS code (G0103) description for screening PSA tests limits use to the total prostate specific antigen test (tPSA), which was the only screening PSA test approved by the FDA at the time HCPS code G0103 was created in 2000 to implement the new Medicare benefit for prostate cancer screening. Bayer is working with CMS in seeking a change to coverage language for the complexed prostate specific antigen assay. This test has CPT code 84152, but Bayer would like physicians to be able to have a revenue neutral option for deciding which test to choose. Bayer is requesting the establishment of a HCPCS code that can be used to report the cPSA test under Medicare's benefit, which now addresses the total PSA.

HCPCS Meeting Agenda Item #11
June 7, 2006
Request #06.122

Topic/Issue:
Request to establish three (3) codes for substance abuse treatment services**.** Requester suggested language**:** 1) Alcohol and other drug screening, 2) Alcohol and other drug screening and brief advice, and 3) Alcohol and other drug brief intervention.

Background/Discussion:
According to the requester, screening, brief intervention, and referral to treatment (SBIRT) programs have been implemented that utilize the clinical and cost-effectiveness research that has been published in the last several years, and include a report by the National Academy of Sciences Institute of Medicine that adapted the study Crossing the Quality Chasm for mental illnesses and substance use disorders. The research has been used to implement screening and brief interventions through the World Health Organization, the SAMHSA 14-site State SBIRT and the 10-site SBIRT college campus health clinic programs in the United States. "Clinics and hospitals have expressed interest in implementing these procedures on a large scale across all facilities in a state for example, but are unable to move in that direction due to current coding conventions." Under current procedure codes for screening only, CMS permits only one screening per year. In addition, these codes cannot be used on the same day by more than one clinician in the same setting and they cannot be used on the same day in more than one setting.

According to the applicant, existing code H0002 BEHAVIORAL HEALTH SCREENING TO DETERMINE ELIGIBILITY FOR ADMISSION TO TREATMENT is inappropriate because it describes screening for the purpose of admission; and T1023 SCREENING TO DETERMINE THE APPROPRIATENESS OF CONSIDERATION OF AN INDIVIDUAL is inappropriate because it is used to screen for admission to determine appropriateness for participation in a specific program. H0004 BEHAVIORAL HEALTH COUNSELING AND THERAPY, PER 15 MINUTES is also inappropriate because it is a treatment code. Under current procedure codes for screening only, CMS permits only one screening per year.

CMS HCPCS Workgroup Preliminary Decision:
Use existing code H0001 "ALCOHOL AND/OR DRUG ASSESSMENT", H0002 "BEHAVIORAL HEALTH SCREENING TO DETERMINE ELIGIBILITY FOR ADMISSION TO TREATMENT PROGRAM", or H0047 "ALCOHOL AND/OR OTHER DRUG ABUSE SERVICES, NOT OTHERWISE SPECIFIED", as appropriate, to identify the service. Inquiries regarding coverage and payment are not within the purview of the HCPCS code set maintainers. CMS suggests that such inquiries be submitted to the individual insurers.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
There was no Primary Speaker for this item.

HCPCS Meeting Agenda Item #12
June 7, 2006
Request #06.137

Topic/Issue:
Request to establish a code for a hygienic bowel/rectal access and management, trade name: Zassi Bowel Management System™.

Background/Discussion:
According to the requester, Zassi is a unique system designed to protect patients, caregivers, and facilities from fecal contact and contamination. The Zassi system is not a passive fecal collection or an ostomy product. It is cleared for drug and irrigation delivery directly to the accessed colon and rectum. It is intended for overall bowel management, such as the diversion of fecal matter to minimize contact with patient skin; to facilitate closed system collection; and to provide access for colonic irrigation and drug administration. The Zassi System can be used for up to 29 days and the drug/irrigation delivery port can be accessed as many times as needed while the catheter is in use. The system also includes a drainable collection bag which can be used up to 10 days. Optional single use collection bags are also available. A compatible gravity irrigation bag is also available, and is changed daily.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to identify this bowel management system. It is a convenience item. For Medicare, there is no benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
There was no Primary Speaker for this item.

HCPCS Meeting Agenda Item #13
June 7, 2006
Request #06.140

Topic/Issue:
Request to establish a code for an electronic medical record smart card, trade name: Medical Messenger.

Background/Discussion:
According to the requester, Medical Messenger is an innovative, highly secure, electronic medical record service product. The key to the product is a secure "smart card" system, which is subscribed to by the patient and allows fast access to an individual's medical records by medical professionals. The system provides patients with better health care by providing access to their medical records by health care professionals and provides the doctor with an easy to use, state-of-the-art digital information technology system at no cost for hardware or software. Medical Messenger even provides manpower for the arduous task of entering patient data into the system during start-up. Access is provided by the Medical Messenger's "four doors": 1) smart card imbedded with the Mifare K1 chip accessing the data by virtual private network, 2) internet access which requires three identifiers that HIPAA mandates in order for secure query, 3) fax back system in which remote medical personnel call 800# and relay patient's three HIPAA identifiers; medical messenger personnel on a 24 x 7 service accesses the data base and faxes the records to the calling party and 4) physician's personal tablet computer with both Wi-Fi and CDMA connectivity. Applicant suggests that code language cover the four doors mentioned above.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this item. It is not primarily medical in nature. For Medicare, there is not benefit category, and code A9270 "NON-COVERED ITEM OR SERVICE" should be used. For coding guidance for other insurers, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid agency in the state in which a claim would be filed. For private insurance, contact the individual private insurance contractor.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
There was no Primary Speaker for this item.

HCPCS Meeting Agenda Item #14
June 7, 2006
Request #06.142

Topic/Issue:
Request to establish a new code for a silicone based product that is added to burn compression garments, orthoses, and TFOs, TFNOs and TNOs, trade name: Silon.

Background/Discussion:
According to the requester, Silon is used in conjunction with pressure garments, orthoses, burn masks i.e. total contact facial orthoses TFOs, total contact face/neck orthoses TFNOs, and total contact neck orthoses TNOs. It has been a widely used clinical management option for treatment of hypertrophic scars and keloids post skin graft, skin flap, wound closure, and burn injuries since the early 1980s. Clinical reports maintain that the use of silicone bonded directly to high and low temperature plastics and textiles aids in scar management through wound hydration, reduction of shear and or tension to the wound secondary to range of motion, contracture management, and patient movement. The addition of silicone materials has been beneficial in treating patients who cannot tolerate the pain of traditional garments and orthoses. Incorporating a soft silicone barrier may reduce the shear forces of the fabric and or plastic material against the skin in addition to functioning as an anti-adhesive dressing to aid in shock absorption to prevent additional trauma to the injured site. Applicant's recommended language for the requested code is "Addition to compression burn garment and or compression burn mask, face and/or neck, plastic or equal, custom fabricated of silicone material/lining". The requester is seeking an "add-on" code for use with burn compression garment codes A6501-A6512 and total contact face orthosis code A6513

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a new code to separately identify silicone. Existing burn garment codes include the materials of manufacture; therefore use of an add-on code is inappropriate. Use existing burn garment codes as appropriate.

Medicare Payment:
Fee schedule and payment rules associated with existing codes apply to these products.
Pricing = 35

Primary Speaker:
There was no Primary Speaker for this item.

HCPCS Meeting Agenda Item #15
June 7, 2006
Request #06.01

Topic/Issue:
Request to establish a code for material that covers oxygen tubing, trade name: Comfeeze.

Background/Discussion:
Romaine Settle of RoMed LLC submitted a request to establish a code for material that covers oxygen tubing, trade name: Comfeeze. According to the requester, Comfeeze is a soft piece of material that is secured around the oxygen tubing at the site of the ears with Velcro that prevents sores and infections at the site of the ears, helps to heal sores already formed, and provides comfort.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this item. It is not primarily medical in nature. For Medicare, there is no benefit category and code A9270 "NON-COVERED ITEM OR SERVICE", should be used and use of miscellaneous codes is inappropriate. For guidance regarding appropriate coding 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 would be filed.

Medicare Payment:
This item is not covered by Medicare.
Pricing = 00

Primary Speaker:
There was no Primary Speaker for this item.

HCPCS Meeting Agenda Item #16
June7, 2006
Request #06.41

Topic/Issue:
Request to establish a code for a biolpar radiofrequency percutaneous discectomy probe, trade name: Perc ™ DLR Spine Wand™, Perc DLG

Background/Discussion:
According to the requester, the Perc D Spine Wand is a single-patient use, disposable medical device used for ablation, coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs. A 17-gauge needle is inserted into the patient's disc under fluoroscopic guidance. The SpineWand is introduced through the needle and uses bipolar radiofrequency energy to remove tissue via plasma molecular dissociation. This radiofrequency energy excites the electrolytes in a conductive medium such as saline solution, creating precisely focused plasma. The energized particles in the plasma have sufficient energy to break the molecular bonds, excising or dissolving soft tissue at relatively low temperatures, thereby preserving the integrity of the surrounding healthy tissue. The result is a portion of the nucleus tissue is gently removed, decompressing the herniated disc.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to separately identify this product. Payment for this device is included with the procedure, and therefore the device is not separately billable. For Medicare, when performed in an in-patient setting, the procedure is included in the DRG. In OPPS, the device is bundled into the procedure payment, although the device is reportable using C2614 "PROBE, PERCUTANEOUS LUMBAR DISCECTOMY". For coding guidance for other insurers, contact the insurer in whose jurisdiction a claim would be filed. For private insurance, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed.

Primary Speaker:
There was no Primary Speaker for this item.

HCPCS Meeting Agenda Item #17
June 7, 2006
Request #06.88

Topic/Issue:
Request to establish a code for an intravascular pressure-measuring interventional guidewire, trade name: PressureWire®.

Background/Discussion:
According to the requester, the PressureWire is used in patients undergoing catheterization to determine the severity of an arterial stenosis, either coronary or non-coronary (e.g., renal). When used in coronary settings in combination with aortic pressure at maximum hyperemia, the PressureWire provides the value for Fractional Flow Reserve (FFR), which will assist the physician in determining if an assessed lesion is culprit. The PressureWire is a 0.014" diameter high-torque interventional guidewire available in either 175 cm or 300 cm shaft lengths. The guidewire connects to the RADIAnalyzer monitor via a connector cable. The 3-cm tip of the wire is composed of an easy-to-shape platinum spring around a central core wire. At the proximal end of this tip is a high fidelity pressure transducer that accurately and precisely measures intracoronary pressure. In addition, the PressureWire includes a PTFE-coated shaft that provides lubrication and enhances handling. According to the requester, physicians will not shift FFR and Coronary Flow Reserve (CFR) services from hospitals to cath labs without a corresponding payment for the cost of acquiring the PressureWire device, and cath lab services cannot be covered by an inpatient payment mechanism or an outpatient facility fee.

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to establish a code to identify this device. It is included in the practice expense, and is not separately payable, although code C1769 is reportable when the procedure is performed in an outpatient setting. CMS recommends that the applicant separately submit an inquiry to the American Medical Association (AMA) practice expense advisory committee regarding inclusion of the wire when it is used in the procedure.

Primary Speaker:
There was no Primary Speaker for this item.

PAYMENT FOR DMEPOS

DMEPOS

The term DMEPOS, which stands for durable medical equipment (DME), prosthetics, orthotics and supplies, is used in the Medicare program to describe a set of Medicare Part B device and supply benefits for which claims are processed by four DME Regional Carriers (DMERCs). The Part B device benefits covered by this term include:

- DME – equipment used in the home which can withstand repeated use, is primarily and customarily used to serve a medical purpose, and is generally not useful in the absence of an illness or injury;
- Prosthetic Devices – devices that replace all or part of an internal body organ, including ostomy, tracheostomy and urological supplies, parenteral and enteral nutrients, equipment and supplies (PEN), intraocular lenses (IOLs), and one pair of conventional eyeglasses or contact lenses after each cataract surgery;
- Prosthetics – artificial legs, arms, and eyes;
- Orthotics – rigid or semi-rigid leg, arm, back, and neck braces;
- Home Dialysis Supplies and Equipment
- Surgical Dressings
- Therapeutic Shoes and Inserts

Depending on the item or the setting in which the item is furnished, Medicare claims for some of these items may also be processed by local carriers and fiscal intermediaries (e.g., claims for DME implanted in an ambulatory surgical center are processed by local carriers). Claims for DME and ostomy, tracheostomy and urological supplies furnished by a home health agency are processed by Regional Home Health Intermediaries (RHHIs).

Fee Schedule Payments

Prior to January 1, 1989, payment for most DMEPOS items and services was made on the basis of the reasonable charge methodology. Reasonable charges are calculated using suppliers' charges and are limited by an inflation adjustment factor. Payment is still made on a reasonable charge basis for home dialysis supplies and equipment and for IOLs inserted in a physician's office. There is a monthly limit per beneficiary on payments for home dialysis supplies and equipment. Payment for most of the other DMEPOS items and services is based on the lower of the actual charge for the item or a fee schedule amount. The Part B deductible and 20 percent coinsurance both apply to the DMEPOS items and services described above.

The Social Security Act requires that the DMEPOS fee schedule amounts be established based on average reasonable charges made during a base period (e.g., July 1, 1986 thru June 30, 1987 for prosthetic devices, prosthetics and orthotics). The fee schedule amounts are increased by annual update factors. Because the reasonable charge data required by the law in establishing fee schedule amounts does not exist for new DMEPOS items, the fee schedule amounts for new DMEPOS items are "gap-filled" using fees for comparable items, supplier price lists, manufacturer suggested retail prices, or wholesale prices plus a markup. The gap-filling methodology is used to estimate the average reasonable charge for the item from the base period.

DMEPOS Payment Categories/HCPCS Pricing Indicators

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicators in the HCPCS identify which major payment category a code falls under. The pricing indicators applicable to DMEPOS are as follows:

- **Pricing = 00 Service Not Separately Priced**
  Items or services described by the HCPCS codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.

- **Pricing = 31 Frequently Serviced Items**
  Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient's health.

- **Pricing = 32 Inexpensive and Other Routinely Purchased Items**
  Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of $150 or less, are generally purchased 75 percent of the time or more, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or intermittent assist device with continuous airway pressure device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

- **Pricing = 33 Oxygen and Oxygen Equipment**
  Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. An additional payment is made for those beneficiaries who require portable oxygen. The beneficiary takes over ownership of the equipment after the 36th monthly payment is made, after which payment for delivery of contents continues for patient owned gaseous or liquid systems.

- **Pricing = 34 Supplies Necessary for the Effective Use of DME**
  Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

- **Pricing = 35 Surgical Dressings**
  Payment is made on a purchase fee schedule basis for surgical dressings.

- **Pricing = 36 Capped Rental Items**
  Payment is made on a monthly rental fee schedule basis. For items furnished on or after January 1, 2006, the beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. Power wheelchairs can be purchased in the first month.

- **Pricing = 37 Ostomy, Tracheostomy and Urological Supplies**
  Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

- **Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)**
  Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

- **Pricing = 39 Parenteral and Enteral Nutrition (PEN)**
  Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

- **Pricing = 45 Customized DME**
  Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item.

- **Pricing = 46 Carrier Priced Item**
  For items falling under codes for miscellaneous or not otherwise classified items, the fee schedule or reasonable charge payment amount, whichever is applicable, is based on the carrier's individual consideration of the item.

- **Pricing = 52 Reasonable Charges**
  Payment continues to be made on a reasonable charge basis in accordance with Medicare regulations at 42 CFR 405.500 for splints, casts, and other devices used to reduce a fracture or dislocation, dialysis supplies and equipment, and intraocular lenses (IOLs) inserted in physician's offices.