Centers for Medicare & Medicaid Services (CMS)
HCPCS Public Meeting Summary Report for:
Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents Public Meeting
June 15, 2006

Public Meeting Introduction and Overview

Denise Bailey-Jones, CMS Office of Operations Management, moderated the meeting. Approximately 65 people attended. The agenda included 22 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.

Amy Bassano 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 15, 2005
HCPCS Request #05.01

Background/Discussion:

Stuart Murray of Cubist Pharmaceuticals, Inc. submitted a request to establish a code for daptomycin for injection, trade name: Cubicin. According to the requester, Cubicin is used for the treatment of complicated skin structure infections caused by Gram-positive bacteria. This antibacterial agent is from a new class of antibiotics called cyclic lipopeptides. The active ingredient in Cubicin is daptomycin. Daptomycin causes rapid depolarization of the bacterial membrane, leading to cessation of bacterial DNA, RNA, and protein synthesis and resulting in bacterial cell death. Cubicin is administered intravenously. Recommended dosage is 4mg/kg administered over a 30-minute period by intravenous infusion in 0.9% sodium chloride injection once every 24 hours for 7 to 14 days. Cubicin is supplied in single-use vials containing 500mg daptomycin as a sterile, lyophilized powder.

CMS HCPCS Workgroup Preliminary Decision: To use newly established code J0878 injection daptomycin, 1mg. (established January 1, 2005).

There was no Primary Speaker for this item.

Meeting Agenda Item #2
June 15, 2005
HCPCS Request #05.27

Background/Discussion:
Stephen McGill of Novo Nordisk has submitted a request to change Q0187 to a J code and to change the dosage from "per 1.2 mg" to "per microgram". Q0187 currently reads: FACTOR VII A (COAGULATION FACTOR, RECOMBINANT) PER 1.2MG. The applicant has requested this change to a J code to be consistent with the other clotting factors used by hemophilia patients. In addition, although the drug is packaged in 1.2 mg. vials, it is administered in microgram doses. According to the requester, NovoSeven Coagulation Factor VIIa (recombinant) is indicated for treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX and is the only approved recombinant FVIIa for effective, reliable treatment of bleeding episodes in this patient population. It is intended for intravenous bolus administration. The recommended dose of NovoSeven is 90ug/kg given every two hours until hemostasis is achieved or until the treatment has been judged to be adequate.

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

J???? Factor VII A (antihemophilic factor, recombinant), per 100 mcg.

Discontinue Q0187.

Primary Speaker – Thomas Schoenwalder of Novo Nordisk. Nova Nordisk thanks the Workgroup for considering its request, requested that the dose descriptor for the code proposed by CMS be changed to "per 1mcg", as opposed to "per 100 mcg" as proposed by CMS.

Mr. Schoenwalder asked that NovoSeven® be treated like other clotting factors to circumvent billing and payment problems

- Units reflected in the descriptor should be consistent with other clotting factors and with the CMS furnishing fee
- Novo Nordisk respectfully requests a permanent HCPCS code for NovoSeven® with a descriptor of *Factor VIIA (antihemophilic factor, recombinant), per 1 mcg*

Meeting Agenda Item #3
June 15, 2005
HCPCS Request #05.36

Background/Discussion:

Deanna Darlington of Pharmion Corporation has submitted a request to establish a code for azacitidine for injectable suspension, Trade Name: Vidaza ™. According to the requester, Vidaza™ contains azacitidine, a pyrimidine nucleoside analog of cytidine. It is classified as an antimetabolite by the FDA and is the only treatment commercially available to treat the five sub-types of Myelodysplastic Syndrome. It is believed to exert its antineoplastic effects primarily through hypomethylation of newly synthesized DNA. Methylation is an epigenetic mechanism by which gene expression may be switched off in certain cell types. Patterns of methylation vary within tissue and cell type. It is supplied in a sterile form for reconstitution and subcutaneous injection only. Vials of Vidaza contain 100mg. Of azacitidine and 100mg. Mannitol as a sterile lyophilized powder. The recommended starting dose of Vidaza is 75mg/m2 subcutaneously, daily for seven days, every four weeks. It may be increased to 100mg/m2 if no beneficial effect is seen after two treatment cycles and if no toxicity other than nausea and vomiting has occurred. It is recommended that patients be treated for a minimum of 4 cycles, although complete or partial response may require more than 4 treatment cycles. It may be continued as long as the patient continues to benefit.

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

J???? Injection, azacitidine, 1 mg

Discontinue C9218.

Primary Speaker – Dr. James Rossetti, D.O., agreed with preliminary decision and language.

Meeting Agenda Item #4
June 15, 2005
HCPCS Request #05.38

Background/Discussion:

Marie DiFiore of Bracco Diagnostics has submitted a request to establish a code for Sincalide lyophilized powder for injection, Trade Name: Kinevac®. The applicant proposed the following code language: JXXXX – Injection, Sincalide USP, per 5 mcg. According to the requester, Sincalide is labeled to stimulate contraction of the gallbladder prior to cholecystography with contrast media, ultrasonography, or duodenal aspiration of bile. Sincalide is also labeled to stimulate pancreatic secretions in conjunction with secretin prior to duodenal aspiration and to speed the gastrointestinal transit of barium meals. Sincalide is a synthetic octapeptide, pharmacologically similar to cholecystokinin. Both agents increase intestinal motility and cause gallbladder contractions, reducing gallbladder size and causing bile evacuation. Sincalide also stimulates the acinar cells of the pancreas and can potentiate the pancreatic effects of secretin.

CMS HCPCS Workgroup Preliminary Decision: No new code. Use existing CPT code.

No insurer identified a national program operating need to alter the existing HCPCS code set to separately identify this item that is bundled into the practice expense of a CPT code. For guidance regarding appropriate coding, contact the insurer in whose jurisdiction a claim would be filed. For Medicare, this item is included in a bundled payment in HOPPS; and included in the practice expense associated with the appropriate CPT code when provided in a physician's office. Use of code J3490 is not appropriate. 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 – Marie DiFiore, disagreed with preliminary decision, believes that Kinevac should have a distinct HCPCS code. Request based upon new labeling change that includes cholescintigraphy (nuclear medicine), where 80% of Kinevac is used. Establishing separate coding and billing is consistent with other pharmaceutical drugs used in hepatobiliary and other nuclear medicine procedures.

Meeting Agenda Item #5
June 15, 2005
HCPCS Request #05.39

Background/Discussion:
Juliana Reed of Baxter Healthcare submitted a request to establish a code for frozen premix penicillin G potassium for injection. According to the requester, Penicillin G Potassium in Plastic Container, herein referred to as Frozen Premix Penicillin G Potassium Injection, USP (equivalent to 1, 2 or 3 million units of penicillin G), is a 50mL, premix, iso-osmotic, sterile, nonpyrogenic, frozen solution for intravenous administration. It is a non-antipseudomonal antibiotic used to treat infections caused by bacteria. It works by killing the bacteria or preventing their growth. Dextrose, USP has been added to the dosages to adjust osmolality (approx. 2g, 1.2g, and 350mg as dextrose hydrous, respectively.) Sodium citrate, USP has been added as a buffer. The pH has been adjusted with hydrochloric acid and may have been adjusted with sodium hydroxide. The pH is 6.5 (5.5 to 8.0). The solution is contained in a single dose GALAXY container. This GALAXY container is fabricated from specially designed multilayer plastic (PL 2040 Plastic).

CMS HCPCS Workgroup Preliminary Decision: To use existing codes J2540 (injection, penicillin G potassium, up to 600,000 units) to identify the penicillin G potassium and J7051 (sterile saline or water, up to 5cc) to identify the diluent, Note: J7051 may be converted to an "A" code in January, 2006.

While a frozen premix solution may provide a convenience factor for administration, the drug being administered is Penicillin G Potassium, which is identified by existing code J2540. No insurer identified a national program operating need to alter the existing code set to separately describe this drug in a frozen premix form and package. It is inappropriate to use J3490 or any other miscellaneous code to identify this item.

Primary Speaker – Dr. John Wesley, M.D., disagreed with the preliminary decision and reiterated the request for distinct codes to identify pre-mix products based on the following claims:

- Premix drug products are distinct and unique because they constitute a closed delivery system which enhances safety, reduces medication errors, and improves patient outcomes.
- Scientific studies support the fact that a closed delivery system is the safest form of intravenous drug administration.
- National clinical practice standards (JCAHO and USP) support the use of premix drugs to reduce contamination and ensure patient safety.
- The safest form of intravenous drug administration is critical as care shifts to outpatient settings.
- Closed delivery systems are not a matter of convenience but inherently provide a safe environment for Medicare beneficiaries receiving intravenous drug administration.

Meeting Agenda Item #6
June 15, 2005
HCPCS Request #05.40

Background/Discussion:
Juliana Reed of Baxter Healthcare submitted a request to establish a code for frozen premix vancomycin injection U.S.P. According to the requester, Vancocin® HCL in Plastic Container, herein referred to as Frozen Premix Vancomycin Injection, USP, is frozen iso-osmotic, sterile, nonpyrogenic premixed 100 mL or 200 mL solution containing 500mg or 1 g Vancomycin, USP respectively as Vancomycin Injection, USP. It is a tricyclic glycopeptide antibiotic derived from Amycolatopsis orientalis. It is used to treat infections in many different parts of the body. It is sometimes given with other antibiotics. Vancomycin given by injection is used mainly for serious infections for which other medicines may not work. The drug product is an antibiotic used primarily to treat susceptible strains of methicillin-resistant staphylococci.

CMS HCPCS Workgroup Preliminary Decision: To use existing codes J3370 (injection, vancomycin hcl, 500mg) to identify the vancomycin and J7051 (sterile saline or water up to 5cc) to identify the diluent, Note: J7051 may be converted to an "A" code.

While a frozen premix solution may provide a convenience factor for administration the drug being administered is vancomycin, which is identified by existing code J3370. No insurer identified a national program operating need to alter the existing code set to separately describe this drug in a frozen premix form and package. It is inappropriate to use J3490 or any other miscellaneous code to identify this item.

Primary Speaker – same as request #05.39 above.

Meeting Agenda Item #7
June 15, 2005
HCPCS Request #05.41

Background/Discussion:
Deborah Walton of Valera Pharmaceuticals, Inc., has submitted a request to establish a code J92xx for histrelin implant, Trade Name: Vantas. According to the requester, Vantas is a sterile, nonbiodegradable, diffusion-controlled, reservoir drug delivery system designed to deliver histrelin continuously for 12 months upon subcutaneous implantation. The Vantas implant contains 50mg of histrelin acetate. Histrelin acetate is a synthetic nonapeptide analogue of the naturally occurring gonadotropin releasing hormone (GnRH) or luteinizing hormone releasing hormone (LH-RH). The sterile Vantas implantation device (provided in the implantation kit shipped with the implant) is used to insert the implant subcutaneously in the inner aspect of the upper arm. After 12 months, the implant must be removed, at which time another may be inserted to continue therapy for an additional 12 months.

CMS HCPCS Workgroup Preliminary Decision: Code C9399 (unclassified drugs or biologicals) is available for use in HOPPS. Establish a new "J" code.

J???? Histrelin implant, 50mg

There was no Primary Speaker for this item.

Meeting Agenda Item #8
June 15, 2005
HCPCS Request #05.44

Background/Discussion:
Jonathan Williams, M.H.A., of Lash Group Healthcare Consultants, has submitted a request to establish a code for pegaptanib sodium injection, Trade Name: Macugen®. The language suggested by the applicant is JXXXX Pegaptanib sodium injection, 0.3 mg. According to the requester, Macugen is used in the treatment of neovascular (wet) age-related macular degeneration (AMD). Pegaptanib is a selective vascular endothelial growth factor (VEGF) antagonist. VEGF is a secreted protein that selectively binds and activates its receptors located primarily on the surface of vascular endothelial cells. It induced angiogenesis and increases vascular permeability and inflammation, all of which are thought to contribute to the progression of the neovascular form of age-related macular degeneration. It is supplied in a single-dose, pre-filled syringe and is formulated as a 3.47 mg/mL solution to deliver a dose of 0.3 mg pegaptanib in a nominal volume of 90µL. It is administered via an intravitreal injection.

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

J???? Injection, pegaptanib sodium, 0.3 mg

There was no Primary Speaker for this item.

Meeting Agenda Item #9
June 15, 2005
HCPCS Request #05.46

Background/Discussion:

Elizabeth Spurgin of Aventor Reimbursement has submitted a request to modify the verbiage of code J7616 ALBUTEROL, UP TO 5 MG AND IPRATROPIUM BROMIDE UP TO 1 MG, COMPOUNDED INHALATION SOLUTION, ADMINISTERED THROUGH DME to instead read ALBUTEROL, UP TO 2.5 MG AND IPRATROPIUM BROMIDE UP TO 0.5 MG, IN PREMEASURED AND PREMIXED VIAL, INHALATION SOLUTION, ADMINISTERED THROUGH DME to specifically exclude inhalants compounded by a pharmacy, and to describe a single dose. The issue involves DuoNeb® Inhalation Solution, which is a dual-therapy nebulizer solution for the treatment of bronchospasm associated with COPD for patients requiring more than one bronchodilator. DuoNeb combines two proven respiratory solutions in one premixed, premeasured, 3mL unit dose vial for nebulization: albuterol sulfate and ipratropium bromide. It is supplied in a 3mL sterile solution for nebulization in sterile low-density polyethylene unit-dose vials, packaged as either single vial or cards of 5 vials in foil packages.

CMS HCPCS Workgroup Preliminary Decision:

1) Discontinue code J7616. Eff. 12/31/05

2) Establish a new "J" code.

J???? Albuterol, up to 2.5 mg and ipratropium bromide up to 0.5 mg, non-compounded inhalation solution, administered through DME.

3) For compounded preparations, use individual "J" codes with KP and KQ modifiers

Primary Speaker – Paul Campbell, agreed with the preliminary decision however, he suggests that the description contained in the preliminary decision be accompanied by the current HCPCS code dosage which is defined as one single dose unit.

Meeting Agenda Item #10
June 15, 2005
HCPCS Request #05.47

Background/Discussion:
Elizabeth Spurgin of Aventor Reimbursement has submitted a request to discontinue code J7617. The requestor believes that J7617 does not describe any item or service that is currently on the market, and the existence of this code could encourage inappropriate pharmacy compounding.

CMS HCPCS Workgroup Preliminary Decision: To discontinue code J7617.

The code J7617 is duplicative. For compounded preparations, use individual "J" codes with KQ and KP modifiers.

Primary Speaker – Paul Campbell agreed with the preliminary decision.

Meeting Agenda Item #11
June 15, 2005
HCPCS Request #05.48

Background/Discussion:
James Coccia of Genzyme Corporation submitted a request to establish a code for clofarabine, Trade Name: CLOLAR™. According to the requester, CLOLAR™ is indicated for the treatment of pediatric patients 1 to 21 years old with refractory or relapsed acute leukemia. Clofarabine is sequentially metabolized intracellularly to the 5' –monophosphate metabolite by deoxycytidine kinase and mono- and di-phosphokinases to the active 5' –triphosphate metabolite. Conversion of the monophosphate to the diphosphate is the rate-limiting step resulting in cellular accumulation of both clofarabine mono- and tri-phosphate. Clofarabine has high affinity for the activating phosphorylating enzyme, deoxycytidine kinase, equal to or grater than that of the natural substrate, deoxycytidine. CLOLAR™ has demonstrated anti-cancer activity through inhibition of DNA synthesis and repair, introduction of apoptosis, and possibly through other mechanisms.

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

J???? Injection, clofarabine, 1mg

Primary Speaker – Blaine McKee strongly supports the preliminary decision to grant a unique J-code to clofarabine. Granting a new code is consistent with established HCPCS coding principles and prior HCPCS coding decisions on oncology products, and will facilitate the proper processing by clinicians and payors.

Meeting Agenda Item #12
June 15, 2005
HCPCS Request #05.53

Background/Discussion:

Amar Singh of Abraxis Oncology submitted a request to establish a code for Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound), Trade Name: ABRAXANE™ for Injectable Suspension. According to the requester, ABRAXANE™ is the first in a novel class of solvent-free compounds that combines human albumin with an active pharmaceutical agent (paclitaxel) in the nanoparticle state. This novel form of drug reduces toxicity and enhances efficacy by increasing intra-tumoral concentration of the drug while sparing normal tissue. ABRAXANE™ is an anti-cancer chemotherapeutic agent that inhibits microtubule formation, thereby killing rapidly dividing cancer cells. Each single-use vial of ABRAXANE™ contains 100mg of paclitaxel and approximately 900 mg of human albumin. Each milliliter of reconstituted suspension contains 5mg of paclitaxel. This formulation is free of solvents. ABRAXANE™ is a cytoxic anti-cancer drug given via intravenous infusion of 260mg/m² over 30 minutes every three weeks. Unlike other taxanes, no premedication is required prior to administration.

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

J???? Injection, paclitaxel protein-bound particles, 1 mg.

Until the new code is established, use C9127 for HOPPS.

Primary Speaker – Michael Hawkins, MD, agreed with preliminary decision to establish a new "J" code.

Meeting Agenda Item #13
June 15, 2005
HCPCS Request #05.55

Background/Discussion:

Joseph J. Canny of Watson Pharma, Inc. has submitted a request to establish a unique code for Iron Dextran Injection, USP, Trade Name: INFeD®. According to the requester, INFeD® is FDA approved for the treatment of patients with documented iron deficiency in which oral administration is unsatisfactory or impossible. INFeD® can be administered intravenously or intramuscularly. The recommended dose for iron-deficiency anemia varies by patient age, gender, and weight and is calculated using the following table that incorporates the patient's desired hemoglobin and observed hemoglobin. It is supplied in 2mL single dose amber vials in cartons of 10, containing 50mg of elemental iron per mL.

CMS HCPCS Workgroup Preliminary Decision: To use existing code J1750 injection, iron dextran, 50mg.

Existing code J1750 adequately describes the product that is the subject of this request. Iron Dextran Injection is in fact a predicate product for the original establishment of HCPCS code J7150. Therefore, a new code is not necessary, and would be duplicative of J1750.

Primary Speaker – Joe Canny on behalf of Watson Pharma, Inc respectfully disagreed with the HCPCS Workgroup's preliminary decision not to issue a new code for INFeD (iron dextran injection, USP). We do not believe J1750 adequately describes INFeD as it is also used to describe Dexferrum (iron dextran injection, USP). While these two products have the same generic name, they are neither generic nor therapeutic equivalents. CMS guidelines state that a code adequately describes a product when it describes products "With no significant therapeutic distinctions from the item in the coding request". In the case of INFeD and Dexferrum there are clinically significant therapeutic distinctions, therefore the same code cannot adequately describe both products. These distinctions are evidenced in FDA's evaluations of the products and in clinical experience. FDA has designated these products as BP rated. A review of the Orange Book listings and HCPCS codes did not find another case where BP rated injectable products hare the same HCPCS code. Because the clinical experience with these products indicates a significant difference in safety profiles, we feel Medicare Beneficiaries may be exposed to additional adverse drug events if these products are not given separate HCPCS codes. Therefore we request that he Workgroup issue separate codes for INFeD and Dexferrum.

Meeting Agenda Item #14
June 15, 2005
HCPCS Request #05.57

Background/Discussion:
Nick Poulios of Elan Pharmaceuticals, Inc. submitted a request to establish a code for zoconotide intrathecal infusion, Trade Name: PRIALT®. According to the requester, PRIALT® (ziconotide intrathecal infusion) is in a new class of non-opioid analgesics called N-type calcium channel blockers (NCCBs) and will be used for the treatment of severe chronic pain, in patients for whom intrathecal (IT) therapy is warranted, and who are intolerant of or refractory to other treatments, such as systemic analgesics, adjunctive therapies or IT morphine. It is a synthetic equivalent of a naturally occurring conopeptide, found in a marine snail known as *Conus magus*. While the mechanism by which PRIALT exerts its anti-nociceptive effect(s) has been well established in animals, the mechanism in humans is not completely known. It is believed that PRIALT relives chronic pain by blocking the release of neurotransmitter signals in the spinal cord. PRIALT does not bind to opioid receptors. PRIALT is formulated as a sterile, preservative-free, isotonic solution. It is then either used undiluted or diluted to the appropriate concentration with 0.9% Sodium Chloride Injection, USP (preservative free).

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

J???? Injection, ziconotide, 1mcg.

Primary Speaker – Dr. Prager, agreed with preliminary decision to establish new "J" code, however, request different language.

- PRIALT is only provided in three single-use vials filled with either 100 mcg or 500 mcg of total drug quantity
- A unit descriptor of 100 mcg is warranted as it represents the lowest number of units that will be billed for PRIALT
- Issuing a billing unit of 100 mcg will reduce Medicare Contractor error rate resulting in reduced costs due to claims reprocessing and appeals
- A permanent J code with a unit descriptor of 100 mcg will facilitate access to PRIALT for Medicare beneficiaries suffering from severe chronic pain
- The following HCPCS code and unit descriptor for PRIALT will accurately reflect usage and support appropriate billing

JXXXX Injection, ziconotide **intrathecal infusion**, 100 mcg

Meeting Agenda Item #15
June 15, 2005
HCPCS Request #05.58A & B

Background/Discussion:

Request #05.58A

Tom Comcowich of RJ Health Systems International, LLC has submitted a request to (A) revise the descriptor of existing code J3303 to add the word "intralesional", and change the strength from "per 5 mg" to "per 0.5 mg", to more accurately describe triamcinolone hexacetonide, trade name: Aristospan, its common use, and billing increments. Also requests (B) a new code for the 20 mg/mL product. According to the requestor, Aristospan is a glucocorticoid (steroid) which exerts an anti-inflammatory activity and is used in a number of different inflammatory conditions. It is injected intralesionally to decrease inflammation.

Request #05.58B

Tom Comcowich of RJ Health Systems International has submitted a request to establish a code for triamcinolone hexacetonide, Trade Name: Aristospan 20mg/mL. According to the requestor, Aristospan is a glucocorticoid (steroid) which exerts anti-inflammatory activity and is used in a number of different inflammatory conditions. It is indicated for use as adjunctive therapy for short-term administration. Aristospan 20mg/mL is injected intra-articularly and is supplied in 1mL and 5mL vials.

CMS HCPCS Workgroup Preliminary Decision:

05.58A
To use existing code J3303 injection, triamcinolone hexacetonide, per 5 mg.

Existing code J3303 adequately describes the product that is the subject of this request. Triamcinolone Hexacetonide is in fact a predicate product for the original establishment of HCPCS code J3303. Appropriate multiples can be reported in the "units" column on a claim form to ensure appropriate reimbursement. A new code is not necessary for identifying the drug or dosage, and would be duplicative of existing J3303.

05.58B
To use existing code J3303 injection, triamcinolone hexacetonide, per 5 mg.

Existing code J3303 adequately describes the product that is the subject of this request. Triamcinolone Hexacetonide is in fact a predicate product for the original establishment of HCPCS code J3303. Appropriate multiples can be reported in the "units" column on a claim form to ensure appropriate reimbursement. A new code is not necessary for identifying the drug or dosage, and would be duplicative of existing J3303.

There was no Primary Speaker for this item.

Meeting Agenda Item #16
June 15, 2005
HCPCS Request #05.59

Background/Discussion:

Christopher Panarites of Scios, Inc. submitted a request to change the description of existing code J2324 from "Injection, nesiritide, *0.25mg*" to "Injection, nesiritide, *0.1mg*. According to the requester, NATRECOR® (nesiritide) is a sterile, purified preparation of a new drug class, human B-type natriuretic peptide (hBNP), and is manufactured from E. coli using recombinant DNA technology. NATRECOR® is a potent vasodilator used to treat acutely decompensated congestive heart failure. NATRECOR® is indicated for the intravenous treatment of patients with acutely decompensated congestive heart failure who have dyspnea (shortness of breath) at arrest or with minimal activity. In this population, the use of NATRECOR® reduced pulmonary capillary wedge pressure and improved dyspnea. According to the applicant, the current dose descriptor of 0.25mg is not sufficiently precise to accommodate individual dosing based on patient weight and intended duration of infusion and other requirements for dose adjustments. In addition, the requested 0.1 mg dose will accommodate the current vial size of 1.5mg as well as the 0.6mg vial now in development, which will meet the needs of most patients and their providers.

C**MS HCPCS Workgroup Preliminary Decision:**

1) Discontinue code J2324.

2) Establish a new "J" code: **J????** Injection, nesiritide, 0.1 mg.

Primary Speaker – Joel Sangerman, Associate Director of Reimbursement, supports the committee's proposal to retire J2324 and replace it with an entirely new code with a volume of 0.1mg.

Meeting Agenda Item #17
June 15, 2005
HCPCS Request #05.61

Background/Discussion:
Gabriele G. Niederauer, Ph.D. of OsteoBiologics, Inc. has submitted a request to establish a code for a Polygraft® BGS Bone Graft Substitute, Trade Name: TruFit® BGS Plug. The requester claims that there is not a CPT-4 code which identifies the particular procedures in which this product is used, and no HCPCS Level II codes to identify the implant. According to the requester, TruFit® BGS Plugs are made of PolyGraft® BGS, which is a proprietary combination of PLA (Polylactic acid), PGA (polyglycolic acid), Calcium Sulfate and trace amounts of surfactant. The production process used to make the TruFit Plugs is also proprietary. The plugs are cylindrical in shape and sized to specifically fit into osteochondral harvest sites or osseous defects created surgically using the TruKor ™ Site Preparation Kit. The TruFit® BGS Plug material acts as a scaffold and provides a protected environment in which new tissue may grow. The surfactant, which makes the material hydrophilic, allows nutrients to be wicked up into the pores and held to encourage growth. The material absorbs over a 9 month period, which is the time necessary to grow into and replace the scaffold.

CMS HCPCS Workgroup Preliminary Decision:
Inappropriate for HCPCS Level II coding. Do not establish a code.

Your request for a code has not been approved. Your product is an integral part of another service, and payment for that service includes payment for your product. The product is bundled in the payment of the surgical procedure for OPPS and as part of the DRG for inpatient use. For ASC use, the product is included in the facility fee. Use of code L8699 and other miscellaneous codes is inappropriate because of the stated bundled payments. You may wish to contact the American Medical Association (AMA) for CPT coding guidance.

There was no Primary Speaker for this item.

Meeting Agenda Item #18
June 15, 2005
HCPCS Request #05.116

Background/Discussion:
Lisa Holmes of AstraZeneca Pharmaceuticals, LP has submitted a request to revise code J7626 or to create a new HCPCS J code with the following requested language: "BUDESONIDE INHALATION SOLUTION, ADMINISTERED THROUGH DME, UNIT DOSE FORM, 0.25 TO 0.50MG NOT TO BE USED TO REPORT ANY SINGLE OR COMBINATION PHARMACY-COMPOUNDED BUDESONIDE PREPARATION", trade name: Pulmicort Respules. According to the requestor, Pulmicort Respules® is indicated for the maintenance treatment of asthma. It is a sterile suspension of a micronized form of budesonide that is specially formulated for inhalation through nebulization. It helps to control asthma by reducing the inflammation that often precipitates an asthma attach or bronchospasm. Improvement in asthma control following treatment can occur within 2 to 8 days of starting treatment, with a maximum benefit in a few weeks. It is the first and only anti-inflammatory corticosteroid formulated for inhalation using a compressed air driven jet nebulizer that is indicated for children between the ages of 12 months and 8 years. It is approved in two strengths: 0.25mg./2mL and 0.5mg./2mL.

CMS HCPCS Workgroup Preliminary Decision: To revise J7626 which currently reads (budesonide inhalation solution, administered through DME, unit dose form, 0.25 to 0.50 mg), to instead read: Budesonide inhalation solution, non-compounded, administered through DME, unit dose form, up to 0.5 mg.

Establish a new "J" code.

J???? Budesonide, powder, compounded for inhalation solution, administered through DME, unit dose form, up to .5 mg.

Primary Speaker – Steve McMillan, Director, Government Reimbursement agreed with the preliminary decisions. AstraZeneca commended the HCPCS Workgroup's preliminary decision to modify the descriptor for J7626 to clarify that this code should not be used to bill for compounded budesonide products.

Meeting Agenda Item #19
June 15, 2005
HCPCS Request #05.117

Background/Discussion:

Joshua Ofman of Amgen USA submitted a request to establish a code palifermin, trade name: Kepivance™. Requested description: INJECTION, PALIFERMIN, PER 6.25 MG. According to the requester, Kepivance is a human keratinocyte growth factor (KGF) produced by recombinant DNA technology in Escherichia coli (E coli). Kepivance is a water-soluble, 140 amino acid protein with a molecular weight of 16.3 kilodaltons. It differs from endogenous human KGF in that the first 23 N-terminal amino acids have been deleted to improve protein stability. Kepivance is indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic stem cell support. The safety and efficacy of Kepivance™ have not been established in patients with non-hematologic malignancies. The recommended dosage of Kepivance is 60 mcg/kg/day, administered as an IV bolus injection for 3 consecutive days before and 3 consecutive days after myelotoxic therapy for a total of 6 doses.

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

J???? Injection, palifermin, 0.1 mg.

Primary Speaker – Roy Baines, MD PhD, agreed with the preliminary decision to establish a new "J" code, however, he recommends to ease the billing burden that the Workgroup select an increment that accords with SKU of 6.25mg (single vial).

Meeting Agenda Item #20
June 15, 2005
HCPCS Request #05.118

Background/Discussion:

Krista Vihma of Lash Group submitted a request to establish a code for etonogestrel contraceptive implant, trade name: Implanon™. Applicant requests the following code description: Jxxxx ETONOGESTREL CONTRACEPTIVE IMPLANT, 68MG. According to the requester, Implanon is a single use, single-rod contraceptive implant that is inserted under the skin of the upper arm. It consists of a non-biodegradeable rod measuring 40 mm in length and 2 mm in diameter. Implanon is inserted just under the skin in the medial aspect of the upper arm 6-8 cm above the elbow crease in the overlying groove between the biceps and triceps muscles. It is inserted by a trained medical professional with a specially designed applicator. Each Implanon rod contains ethylene vinylacetate copolymer core, containing 68mg of the synthetic progestin etonogestrel, surrounded by an EVA copolymer skin. The average hormone release rate is 30-40 micrograms per day. After insertion, the rod slowly releases a progestogenic hormone, etonogestrel which prevents the inhibition of ovulation and thickening of cervical mucosa. Implanon does not contain estrogen, making it suitable for women who do not tolerate or are contraindicated to estrogens. It is used for the prevention of pregnancy in women of reproductive age for up to 3 years.

CMS HCPCS Workgroup Preliminary Decision:

No new code.

We have been notified by the requestor that, 60 days following the March 31st deadline for submission of FDA approval, the FDA has still not approved this item. Therefore, the product did not meet the criteria for coding, and a code will not be established.

There was no Primary Speaker for this item.

Meeting Agenda Item #21
June 15, 2005
HCPCS Request #05.119

Background/Discussion:

Ellen Wallis of CoTherix, Inc. submitted a request to establish a code for iloprost inhalation solution, trade name: Ventavis™, single use ampule. According to the requester, Ventavis is a prostacyclin solution that is administered via inhalation, 6-9 times daily through only the Prodose AAD system, a pulmonary drug delivery device. It is indicated for the treatment of pulmonary arterial hypertension in patients (PAH) with NYHA class III or IV symptoms. Ventavis vasodilates the pulmonary arterial bed leading to significant improvement of pulmonary artery pressure, pulmonary vascular resistance, cardiac output, and mixed venous oxygen saturation. Ventavis delivery is non-invasive; it provides direct delivery to the lungs; it avoids the systemic effects associated with invasive methods of drug delivery; there are no rebound effects associated with the withdrawal of drug; and it avoids significant morbidity/complications associated with the subcutaneous and central venous catheters required for delivery of the invasive prostacyclins. Ventavis is administered via inhalation through the Prodose, a breath-actuated pulmonary drug delivery device and the only device that has been specifically customized to deliver a consistent and accurate dose of Ventavis. The drug is supplied in a single-use ampule containing 2mL/20 mcg of Ventavis inhalation solution. The patient transfers the entire contents of one single-use ampule into the Prodose that administers the drug through the mouthpiece during the patient's normal inhaled breathing pattern.

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

J???? Iloprost, inhalation solution, administered through DME, up to 20 mcg.

Primary Speaker – Ellen Wallis, asked that the words "up to" be removed from the text of the code, so that it would read as temporary code Q4080 currently reads.

Meeting Agenda Item #22
June 15, 2005
HCPCS Request #05.186

Background/Discussion:
Wendy Starr of Cumberland Pharmaceuticals, Inc. submitted a request to establish a code for acetylcysteine, trade name: Acetadote® Injection. According to the requestor, Acetadote is the only FDA-approved intravenous medication for the treatment of acetaminophen overdose. Acetadote is used to prevent or lessen hepatic injury if administered intravenously within 8 to 10 hours after ingestion of a potentially hepatotoxic quantity of acetaminophen. Acetadote likely protects the liver by maintaining or restoring the gluthathione levels, or by acting as an alternate substrate for conjugation with and thus detoxification of, the reactive metabolite.

CMS HCPCS Workgroup Preliminary Decision: No new code.

According to the applicant, this product is used exclusively in the hospital in-patient setting, typically in an ER and intensive care units in an emergent/critical care situation. The product is administered intravenously over a period of hours. This medicine is included in the DRG. Because it is included in the DRG, it is not appropriate to use C9399 or other codes to separately bill for this product.

Primary Speaker – Suzanne Doyon, Medical Director, Maryland Poisan Center. Cumberland Pharmaceuticals doesn't support the Workgroup's preliminary recommendation not to assign a code for Acetadote® for out-patient use.
Additional information:

- Acetylcysteine (p.o. and IV) is the only currently available antidote for the management of acetaminophen overdoses of all types.
- Reduces mortality to 0% in early presenters (<8-10hrs)
- Prevents hepatic injury associated with acetaminophen overdoses.
- FDA-approved Acetylcysteine regimens:
    - 72-hour oral (p.o.) regimen.
    - 20.25-hour continuous intravenous (IV) regimen.

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.

Denise Bailey-Jones also thanked the audience for their participation, and officially adjourned the meeting.