Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Drugs, Biologicals, and Radiopharmaceuticals
Tuesday, May 4, 2010

Introduction and Overview

Approximately 81 people attended. The agenda included 25 items.

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

John Warren, Director of the Division of Ambulatory Services (DAS), provided an overview of the Medicare payment methodology for Part B drugs, biologicals, and radiopharmaceuticals. A copy of the overview was provided in a written document and is attached to this summary.

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

Information provided at the CMS HCPCS Public Meetings is considered by the CMS HCPCS Coding Workgroup at a subsequent workgroup meeting. The Workgroup reconvenes after the public meetings, and reconsiders its preliminary coding recommendations in light of any new information provided, and formulates its final coding decisions.

CMS maintains the permanent HCPCS Level II codes, and reserves final decision making authority concerning requests for permanent HCPCS codes. Final decisions regarding Medicare payment are made by CMS and must comply with the Statute and Regulations. Payment determinations for non-Medicare insurers, (e.g., state Medicaid Agencies or Private Insurers) are made by the individual state or insurer.

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

The latest information on the process for developing agendas and speaker lists for the public meetings, as well as the Guidelines for Proceedings at these CMS' Public Meetings, can be

found on the CMS HCPCS web site, specifically at: http://cms.hhs.gov/medhcpcsgeninfo/08_HCPCSPublicMeetings.asp#TopOfPage. In addition, the standard application format for requesting a modification to the HCPCS Level II Code Set, along with instructions for completion and background information regarding the HCPCS Level II coding process is available at: http://cms.hhs.gov/medhcpcsgeninfo/01_overview.asp#TopOfPage. The application form is updated annually and posted on the CMS HCPSC website sometime in the summer. A decision tree, outlining CMS' decision-making criteria is also available at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/decisiontree.pdf.

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Drugs, Biologicals and Radiopharmaceuticals
Tuesday, May 4, 2010 9:00 am – 5:00 pm
CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

8:15 a.m. Arrival and sign-in

9:00 a.m. Welcome
Background and purpose of meeting
Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS's preliminary coding decision is provided. An overview of Medicare pricing/payment, methodology is also attached to this agenda. Preliminary decisions are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about the agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the general public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. Applicants will be notified of final decisions in November.

The agenda includes a summary of each HCPCS code application on the agenda. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

AGENDA ITEM #1
Attachment#10.003
Request to establish a Level II HCPCS J code for LUSEDRA™ (Fospropofol Disodium) Injection.

No Primary Speaker

AGENDA ITEM #2
Attachment#10.053
Request to establish a code for single-source Epoprostenol for Injection (EFI) Drug, trade name: Veletri (under FDA consideration).

No Primary Speaker

AGENDA ITEM #3
Attachment# 10.018
Request to establish a code for Ecallantide, trade name: Kalbitor®.

Primary Speaker: Dr. Pat Horn of Dyax Corporation

AGENDA ITEM #4
Attachment# 10.026
Request to establish a code for C1 Esterase Inhibitor, trade name Berinert®.

No Primary Speaker

AGENDA ITEM #5
Attachment# 10.084
Request to establish a J code for Immune Globulin Subcutaneous (Human), 20% Liquid, trade name: Hizentra.

No Primary Speaker

AGENDA ITEM #6
Attachment# 10.021
Request to establish a code for Clostridial Collagenase Histolyticum, trade name: Xiaflex™.

No Primary Speaker

AGENDA ITEM #7
Attachment# 10.052
Request to establish a code for von Willebrand Factor/Coagulation Factor VIII Concentrate (Human), trade name: wilate®.

Primary Speaker: Stanley Ammons of Octapharma USA, Inc.

AGENDA ITEM #8
Attachment# 10.065
Request to establish a code Antithrombin, Recombinant, trade name: ATryn.

No Primary Speaker

AGENDA ITEM #9
Attachment# 10.067
Request to establish a code for Canakinumab, trade name: Ilaris® injection for subcutaneous use.

No Primary Speaker

AGENDA ITEM #10
Attachment# 10.017
Request to establish a code for Fludarabine Phosphate 10 mg tablets for oral use, trade name: Oforta™.

Primary Speaker: Dr. Nicholas Sarlis of sanofi-aventis U.S.

AGENDA ITEM #11
Attachment# 10.028
Request to establish a code for ARZERRA™ (Ofatumumab) Injection.

No Primary Speaker

AGENDA ITEM #12
Attachment# 10.038
Request to establish a code for tocilizumab, trade name: ACTEMRA®.

No Primary Speaker

AGENDA ITEM #13
Attachment# 10.074
Request to establish a code for Ustekinumab, trade name: STELARA™.

No Primary Speaker

AGENDA ITEM #14
Attachment# 10.071
Request to establish a code for Romidepsin, trade name: Istodax®.

No Primary Speaker

AGENDA ITEM #15
Attachment# 10.008
Request to establish a new code for Pralatrexate Injection, trade name: Folotyn™.

No Primary Speaker

AGENDA ITEM #16
Attachment# 10.015
Request to establish a code for Lacosamide, trade name: VIMPAT® injection.

Primary Speaker: Chris Clark of UCB, Inc.

AGENDA ITEM #17
Attachment# 10.025
Request to establish a code for Olanzapine for extended release injectable suspension, trade name: Zyprexa® Relprevv™.

No Primary Speaker

AGENDA ITEM #18
Attachment# 10.016
Request to establish a code for Paliperidone Palmitate injection, extended release, trade name: Invega® Sustenna™.

No Primary Speaker

AGENDA ITEM #19
Attachment# 10.036
Request to establish a new code for OZURDEX™ (dexamethasone intravitreal implant) 0.7mg.

Primary Speaker: Dr. Paul Radensky of McDermott, Will & Emery, LLP

AGENDA ITEM #20
Attachment# 10.044
Request to establish a code for QUTENZA® (Capsaicin) 8% patch.

Primary Speaker: Darren Stevens of NeurogesX, Inc.

AGENDA ITEM #21
Attachment# 10.066
Request to establish a code for Methyl Aminolevulinate (MAL) cream 16.8%, trade name Metvixia® Cream 16.8%.

Primary Speaker: Andrew Kloser of Holland & Knight

AGENDA ITEM #22
Attachment# 10.070
Request to establish a code for Telavancin, trade name: Vibativ™.

Primary Speaker: Dr. Mark Villmann of Astellas Pharma Global Development, Inc.

AGENDA ITEM #23
Attachment# 10.085
Request to establish a code for velaglucerase alfa for injection, trade name: VPRIV.

No Primary Speaker

AGENDA ITEM #24
Attachment# 10.033
Request to establish a code to describe aztreonam for inhalation solution, trade name: Cayston.

Primary Speaker: Dr. Ali Toumadj of Gilead Sciences, Inc.

AGENDA ITEM #25
Attachment# 10.005
Request to establish 3 codes to describe Treprostinil inhalation solution, trade name: Tyvaso, and the nebulizer and disposable accessories used with Tyvaso.

No Primary Speaker

HCPCS Public Meeting Agenda Item #1
May 4, 2010

Attachment# 10.003

Topic/Issue:
Request to establish a Level II HCPCS J code for LUSEDRA™ (Fospropofol Disodium) Injection. Applicant's recommended language: "Injection, Fospropofol Disodium, 700 mg."

Background/Discussion:
According to the requester, LUSEDRA (Fospropofol Disodium) a Schedule IV Controlled Substance, is an intravenous, sedative-hypnotic agent indicated for monitored anesthesia care (MAC) sedation in adult patients undergoing diagnostic or therapeutic procedures (e.g., colonoscopy and flexible bronchoscopy). LUSEDRA should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the diagnostic or therapeutic procedure. The FDA recommends the use of supplemental oxygen in all patients undergoing sedation with LUSEDRA. It also recommends continuous monitoring with pulse oximetry, electrocardiogram, and frequent blood pressure monitoring. Facilities for maintenance of a patent airway, providing artificial ventilation, administering supplemental oxygen, and instituting cardiovascular resuscitation should be immediately available. Fospropofol Disodium is a prodrug of propofol. Following intravenous injection, fospropofol disodium is metabolized by alkaline phosphatase. For every millimole of fospropofol disodium administered, one millimole of propofol is produced (1.86 mg of fospropofol disodium is the molar equivalent of 1 mg propofol). LUSEDRA is supplied in single-use vials ready for intravenous injection. Each vial is filled with 32.1 mL of LUSEDRA, 35 mg / mL. Standard dosing: initial intravenous bolus of 6.5 mg / kg body weight followed by supplement doses of 1.6 mg / kg as needed. No initial dose should exceed 16.5 mL. No supplemental dose should exceed 4 mL. A modified dosing regimen (75 percent of standard regimen) may be used for patients 65 years of age or older, or who have severe systemic disease. Adults who weigh over 90 kg should be dosed as if they weigh 90 kg. Adults who weigh less than 60 kg should be dosed as if they are 60 kg. LUSEDRA requires controlled temperature storage. LUSEDRA has the unique generic name, fospropofol disodium. There are also no other drugs marketed with the same active ingredients as LUSEDRA. According to the requester, a unique code should be established to identify Fospropofol because: 1) There is no existing HCPCS code that accurately describes it, and 2) It is not therapeutically equivalent to any other product, as such, it is a "single-source drug" and a unique code is necessary in order to effectuate requirements for payment under Medicare Part B.

CMS HCPCS Preliminary Decision:

A national program operating need to establish a HCPCS Level II code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. CMS suggests that you contact the American Medical Association (AMA) for CPT coding guidance for this product which is used as part of an anesthesia service.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #2
May 4, 2010

Attachment# 10.053

Topic/Issue:

Request to establish a code for single-source Epoprostenol for Injection (EFI) Drug. Trade Name: Veletri (under FDA consideration). Applicant's suggested language: JXXXX (INJECTION, EPOPROSTENOL, SALINE DILUENT, 1.5 MG).

Background/Discussion:

According to the Requester, the FDA has approved EFI for the long-term intravenous treatment of primary pulmonary hypertension and pulmonary hypertension associated with the scleroderma spectrum of disease in NYHA Class III and IV patients who do not respond adequately to conventional therapy. The NDA for EFI, NDA 22-260, was reviewed by the FDA Office of New Drugs, rather than Office of Generic Drugs. The Requester claims that the reconstitution of EFI is different from existing epoprostenol-based products. EFI can be reconstituted with Sterile Water for Injection, USP or Sodium Chloride 0.9 percent injection, USP. Other epoprostenol-based drugs require a special diluent for reconstitution. EFI is a new formulation containing the same active ingredient as other epoprostenol-based drugs, but with different excipients. EFI omits sodium chloride and substitute's arginine for glycine. EFI has a higher pH and reconstituted solutions of EFI are more stable than other epoprostenol-based drugs. EFI is stable at room temperature (77°F) for up to 48 hours, while existing epoprostenol based products are stable at room temperature for no more than 8 hours without the use of frozen gel packs. Unlike other epoprostenol-based products, EFI has USP PET data that characterize the reconstituted solution as bacteriostatic. For these reasons, the requester believes that EPI for injection has no therapeutic equivalents. As such, it should be considered "single-source", and separate payment and a unique HCPCS code is warrented.

CMS HCPCS Preliminary Decision:

Existing code J1325 "INJECTION, EPOPROSTENOL, 0.5 MG" adequately describes the product that is the subject of this request.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #3
May 4, 2010

Attachment# 10.018

Topic/Issue:

Request to establish a code for Ecallantide, trade name: Kalbitor®. Applicant's suggested language: "Ecallantide injection, per 30 mg".

Background/Discussion:

According to the requester, Kalbitor® is a reversible inhibitor of plasma kallikrein for subcutaneous injection for the treatment of acute attacks of hereditary angioedema (HAE) in patients 16 years of age and older. Inhibition of plasma kallikrein reduces formation of bradykinin, a vasodilator associated with increased vascular permeability, edema, inflammation, and pain. By directly inhibiting plasma kallikrein, Ecallantide reduces bradykinin formation and thereby treats symptoms of the disease during acute episodic attacks. Recommended dosage of Kalbitor® is 30 mg administered subcutaneously in three 1 ml injections. If the attack persists, an additional dose of 30 mg (3.0 mL), may be administered within a 24 hour period. Kalbitor® is a sterile solution supplied as 3 vials each containing 1mL of 10 mg/mL Kalbitor packaged in one carton. Vials are intended for single use. According to the requester, a unique HCPCS code is warranted for Kalbitor because: 1) it has a unique generic name, and existing HCPCS codes do not describe this product or active ingredient; 2) Kalbitor meets the statutory definition of single-source drug at SSA§ 1847A(c)(6)(D), and as such, payment must be based on its own ASP, and a unique code will ensure that other drugs are not included in the computation of the ASP for Kalbitor.

CMS HCPCS Preliminary Decision:

Existing code C9263 INJECTION, ECALLANTIDE, 1 MG adequately describes the product that is the subject of this request and is available for assignment by insurers if they deem appropriate.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision and stated that the main place of service for healthcare practitioners to administer Kalbitor® is the physician office setting, where the "C" code cannot be used for reporting on Medicare claims. He also stated that "J" codes have been granted for similar drugs, specifically citing Berinert and Cinryze, which are used for the same condition. The speaker reiterated the original request to establish a "J" code for this product.

HCPCS Public Meeting Agenda Item #4
May 4, 2010

Attachment# 10.026

Topic/Issue:

Request to establish a code for C1 Esterase Inhibitor, trade name Berinert®. Applicant's suggested language: "C1 Esterase Inhibitor (Human), Berinert, each 100 units".

Background/Discussion:

According to the requester, Berinert® is a purified, pasteurized concentrate of C1 Esterase Inhibitor indicated for the treatment of acute facial and abdominal attacks of patients with hereditary angioedema (HAE). C1 inhibitor inactivates its substrate by covalently binding to the reactive site. Administration of Berinert to patients with C1 Esterase deficiency replaces missing or malfunctioning protein in patients to relieve symptoms of HAE. Berinert® is prepared from large pools of human plasma. One standard unit of Berinert® is equal to the amount of C1 inhibitor in 1 mL of fresh citrated human plasma, which is equivalent to 270 mg/L or 2.5 mM/L. The recommended dosage of Berinert® is 20 units per kilogram of body weight for IV injection, administered at a rate of 4mls per minute. It is supplied in a single-use vial containing 500 U of lyophilized concentrate for reconstitution with 10 mL of sterile water for injection. Each carton contains a 500 unit single-use vial of lyophilized Berinert®, one 10 mL vial of diluent, a mix2vial™ transfer set, a disposable 10 mL syringe and one alcohol swab. According to the applicant, "Berinert® qualifies for a unique and separate HCPCS code, since it is a biological product and is not considered to be therapeutically equivalent to any other product. Based on section 1847A of the Social Security Act... part B payment for Berinert must be based on its own ASP."

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, C-1 ESTERASE INHIBITOR (HUMAN), BERINERT, 10 UNITS

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #5
May 4, 2010

Attachment# 10.084

Topic/Issue:

Request to establish a J code for Immune Globulin Subcutaneous (Human), 20% Liquid, Trade Name: Hizentra. Applicant's suggested language: Immune Globulin Subcutaneous, Hizentra, each 100 mg.

Background/Discussion:

According to the Requester, Hizentra® is indicated for the treatment of patients with primary immunodeficiency (PI). It supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial and viral agents. The mechanism of action in Primary Immune Deficiency has not been fully elucidated. Appropriate doses of Hizentra® should restore abnormally low IgG levels to the normal range. Hizentra® is for subcutaneous infusion only. Infusion sites: abdomen, thigh, upper arm, and/or lateral hip. Hizentra® may be infused into multiple injection sites but, no more than 4 sites should be used simultaneously. Multiple injection sites should be at least 2 inches apart. Self-administration of Hizentra® is appropriate for some patients, however it is anticipated that Hizentra will be prescribed for use in all settings. Initial weekly dose in grams (g)= 1.53 x previous IVIG dose (g) divided by the number of weeks between IVIG doses. Multiply the dose in (g) by 5 to convert to the dose in mL. Hizentra® is supplied as 0.2 grams per mL (20%) protein solution for subcutaneous injection in 5, 10, 15 and 20 mL vial sizes. According to the requester, Hizentra® is a single-source drug or biological under SSA §1847A(c)(6)(D) and qualifies for a unique and separate HCPCS code, since it is a biological product (and it is not considered to be therapeutically equivalent to any other product).

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, IMMUNE GLOBULIN (HIZENTRA), 100 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item. Written comments were submitted by the applicant in full support of the preliminary coding decision, but to revise the language of the proposed new code to read as follows: "Injection, Immune Globulin, Subcutaneous (Hizentra), ea 100mg."

HCPCS Public Meeting Agenda Item #6
May 4, 2010

Attachment# 10.021

Topic/Issue:

Request to establish a code for Clostridial Collagenase Histolyticum, trade name: Xiaflex™. Applicant's suggested language: "Collagenase Clostridium Histolyticum, 0.9mg"

Background/Discussion:

According to the requester, Xiaflex™ is a novel therapeutic alternative indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord. Injection of Xiaflex directly into the Dupuytren's cord is intended to lyse the collagen within the cord and ultimately relieve the contracture. Xiaflex™ contains purified collagenase clostridium histolyticum, consisting of two microbial collagenases. Results of invitro studies suggest that the collagenases work in a complimentary manner to provide hydrolyzing activity toward collagen. Injection of Xiaflex™ into a Dupuytren's cord may result in enzymatic disruption of the cord. Xiaflex should only be administered into the Dupuytren's cord with a contracture of a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint according to the injection procedure. The recommended dose is 0.58 mg per injection. For cords affecting metacarpophalangeal (MCP) joints each dose is administered in an injection volume of 0.25mL. For cords affecting proximal interphalangeal (PIP) joints, each dose is administered in an injection volume of 0.20 mL. If a patient has other cords with contractures, physicians are instructed to inject each cord in sequential order with approximately 4-week intervals between single injections. Approximately 24 hours following each injection, a finger extension procedure may be performed if necessary. Injections and finger extension procedures may be administered up to 3 times per cord at approximately 4-week intervals. Xiaflex™ is available in single-use vials containing 0.9 mg of Collagenase Clostridium Histolyticum as a sterile, lyophilized powder to deliver a 0.58 mg dose. Sterile diluent for reconstitution is also provided in a single-use vial. According to the requester, there is no HCPCS code to describe this product.

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, COLLAGENASE, CLOSTRIDIUM HISTOLYTICUM, 0.1 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #7
May 4, 2010

Attachment# 10.052

Topic/Issue:

Request to establish a code for von Willebrand Factor/Coagulation Factor VIII Concentrate (Human); Trade Name: wilate®.

Background/Discussion:

According to the Requester, wilate® is a sterile, lyophilized powder for reconstitution for intravenous injection indicated for spontaneous or trauma induced bleeding episodes in patients with severe von Willebrand Disease (VWD) and patients with mild VWD in whom the use of desmopression is known or suspected to be ineffective or contraindicated. The Von willebrand factor (VWF) in wilate® is derived from normal human plasma and is expected to behave in the same way as endogenous VWF. VWF mediates the binding between platelets and damaged sub-endothelial tissues and is involved in the transport and stabilization of Factor VIII. Thus, administration of VWF allows correction of the hemostatic abnormalities in VWD patients. Dosage of wilate® should be adjusted according to the extent and location of the bleeding. For minor hemorrhages, loading dose is 20-40 IU/kg and maintenance dose is 20-30 IU/kg every 12-24 hours. For major hemorrhages, loading dose is 40-60 IU/kg and maintenance dose is 20-40 IU/kg every 12 - 24 hours. Wilate® is provided in 450 IU vials and 900 IU vials. It differs from similar products in terms of its manufacturing process, virus inactivation methods, and biochemical profile (purity). According to the requester, existing code J7186 "INJECTION, ANTIHEMOPHILIC FACTOR VIII/VON WILLEBRAND FACTOR COMPLEX (HUMAN), PER FACTOR VIII I.U." does not describe this code because is its based on measurements in Coagulation factor VIII units whereas wilate® will be dosed in VWF:RCo units; and code J7187 "INJECTION, VON WILLEBRAND FACTOR COMPLEX (HUMATE-P) , PER IU VWF:RCO" is specific for the product Humate-P.

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, VON WILLEBRAND FACTOR COMPLEX (HUMAN), WILATE, PER 100 IU VWF:RCO

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker supported the Workgroup's preliminary decision to establish a code for Wilate® as well as the proposed code language and dosage descriptor.

HCPCS Public Meeting Agenda Item #8
May 4, 2010

Attachment# 10.065

Topic/Issue:

Request to establish a code Antithrombin, Recombinant, Trade Name: ATryn. Requester's suggested language: Injection, Antithrombin (ATryn), per 100 IU

Background/Discussion:

According to the requester, ATryn is a recombinant Antithrombin for the prevention of peri-operative and peri-partum thromboembolic events in hereditary Antithrombin deficient patients. It is not for treatment of thromboembolic events in hereditary Antithrombin deficient patients. ATryn is not formulated with human plasma proteins. Existing code J7197 (ANTITHROMBIN III (HUMAN), PER I.U.) describes human-derived antithrombin, which is distinct from recombinant Antithrombin. A unique code is needed to recognize ATryn's approval under a new BLA and to ensure appropriate ASP-based payment under Section 1847A of the Social Security Act. Applicant claims that Antithrombin plays a central role in the regulation of hemostasis. The dosage of ATryn is individualized for each patient. Treatment goals are to restore and maintain functional Antithrombin activity levels between 80% - 120% (0.8 – 1.2 IU/mL) of normal. Route of administration: Intravenous infusion. A loading dose is administered as a 15 minute IV infusion, immediately followed by a continuous infusion of the maintenance dose. ATryn is supplied as a sterile, lyophilized formulation. Each vial contains the potency stated on the label, which is approximately 1,750 I.U.

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, ANTITHROMBIN RECOMBINANT, 50 IU

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #9
May 4, 2010

Attachment# 10.067

Topic/Issue:

Request to establish a code for Canakinumab, trade name: Ilaris® injection for subcutaneous use.

Background/Discussion:
According to the requester, Ilaris® is a recombinant, human anti-human-IL-1b monoclonal antibody indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in adults and children 4 years of age and older, including Familial Cold Autoinflammatory Syndrome (FACS) and Muckle-Wells Syndrome (MWS). Excessive release of activated IL-1b drives inflammation. Canakinumab binds to human IL-1b and neutralizes its activity by blocking its interaction with IL-1 recptors. The recommended dose of Canakinumab is 150 mg for CAPS patients with a body weight greater than 40 kg. For patients with a body weight between 15 kg and 40 kg the recommended dose is 2 mg/kg. Doses can be increased to 3 mg/kg for children that weigh between 15 kg to 40 kg with an inadequate response. Canakinumab is administered every eight weeks as a single dose via subcutaneous injection. It is supplied as a carton of 1 single-use vial. Each vial contains lyophilized powder containing 180 mg of Canakinumab that is to be reconstituted with 1 ml of preservative-free sterile water for injection in a 150 mg/ml solution. According to the requester, there is no existing HCPCS code to describe this product.

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, CANAKINUMAB, 1 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #10
May 4, 2010

Attachment# 10.017

Topic/Issue:

Request to establish a code for Fludarabine Phosphate 10 mg tablets for oral use, trade name: Oforta™. Applicant's suggested language: "Fludarabine phosphate tablets, 10 mg".

Background/Discussion:

According to the requester, Oforta™ is a nucleotide metabolic inhibitor indicated as a single agent for the treatment of adult patients with B-cell chronic lymphocytic leukemia (CLL) whose disease has not responded to or has progressed during or after treatment with at least one standard alkylating-agent containing regimen. Oforta™ contains Fludarabine Phosphate, a synthetic purine nucleotide antimetabolite agent. Upon administration, 2F-ara-AMP is rapidly dephosphorylated in the plasma to 2F-ara-A, which then enters into the cell. It is intracellularly incorporated into the DNA where it functions as a DNA chain terminator, inhibits DNA polymerase alpha, gamma, and delta, and inhibits ribonucleoside diphosphate reductase. 2F-ara-A also inhibits DNA primase and DNA ligase I. The mechanism of action of this antimetabolite is not completely characterized and may be multi-faceted. The recommended dosage of Oforta™ is 40 mg/m^2 administered by mouth daily for five consecutive days. The dose is reduced for patients with renal impairment. Effectiveness in pediatric patients has not been established. Dosage may be decreased or delayed based on evidence of hematologic or nonhematologic toxicity. Each 5-day course of treatment should commence every 28 days. The optimal duration of treatment has not been clearly established. It is recommended that three additional cycles of Oforta™ be administered following the achievement of a maximal response and then the drug should be discontinued. Oforta is supplied in 10 milligram tablets containing 10 mg Fludarabine Phosphate. The tablets are supplied in blister strips of 5 tablets, in packages containing 3 to 4 strips of 5 tablets. According to the requester, there is no existing HCPCS code to describe Fludarabine Phosphate tablets for oral use. A new, unique HCPCS code will facilitate patient access to this product and allow payer systems to capture important product-specific data.

CMS HCPCS Preliminary Decision:

1) Newly established code Q2025 FLUDARABINE PHOSPHATE, ORAL, 1 MG (eff. 7/1/10) adequately describes the product that is the subject of this request.
2) Discontinue code Q2025 effective 12/31/10
3) Establish code Jxxxx FLUDARABINE PHOSPHATE, ORAL, 1 MG (eff. 1/1/11)

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker agreed with the Workgroup's preliminary decision to establish a code but disagreed with the 1 MG dosage descriptor. The speaker proposed a revision to the dosage descriptor from "1 MG" to "10 MG". According to the speaker, a 10 MG dosage is optimal because: 1) a 1 MG descriptor is likely to cause claims confusion and reprocessing work for the Medicare DME MACs; 2) the tablets should not be cut, crushed, or chewed; 3) it accommodates the lowest dosage that can be given safely (70mg is the usual dosage); and 4) it follows precedent where the lowest strength is utilized in other oral chemotherapy codes.

HCPCS Public Meeting Agenda Item #11
May 4, 2010

Attachment# 10.028

Topic/Issue:

Request to establish a Level II HCPCS J9xxx code for ARZERRA™ (Ofatumumab) Injection. Applicant's recommended language: "Injection, Ofatumumab, for intravenous infusion, 100 mg."

Background/Discussion:

According to the requester, ARZERRA™ (ofatumumab) is a CD20-directed cytolytic monoclonal antibody that causes the body's immune response to fight against normal and cancerous B-cells. ARZERRA™ injection is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) refractory to fludarabine and alemtuzumab. The recommended dose and schedule for ARZERRA Injection is 12 doses administered by IV infusions follows: 300 mg initial dose, followed 1 week later by 2,000 mg weekly for 7 doses (doses 2 through 8), followed 4 weeks later by 2,000 mg every 4 weeks for 4 doses (doses 9 through 12). ARZERRA™ is supplied at a concentration of 20 mg/mL in 10 mL vials. Each single-use vial contains 100 mg ofatumumab in 5 mL of solution. According to the requester, ARZERRA™ injection represents a new chemical entity approved by the FDA with no substitutions possible by existing FDA-approved drugs, and there are no other drugs marketed with the same active ingredient category/generic name of ofatumumab.

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, OFATUMUMAB, 10 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #12
May 4, 2010

Attachment# 10.038

Topic/Issue:

Request to establish a Level II HCPCS J code for tocilizumab. brand name: ACTEMRA®. Applicant's recommended language: "Injection, tocilizumab, 1 mg.

Background/Discussion:

According to the requester, ACTEMRA® is a recombinant, humanized anti-human interleukin-6 (IL-6) receptor monoclonal antibody. ACTEMRA® differs from other currently marketed biologic RA DMARDs because it targets and competitively blocks IL-6 from binding to its receptor. ACTEMRA® is administered as an injection for intravenous (IV) infusion given once every 4 weeks as a 60-minute single IV infusion. Actemra is indicated for the treatment of Rheumatoid Arthritis (RA) in adult patients with moderately to severely active RA who have had an inadequate response to one or more TNF antagonist therapies. Recommended adult dosage every 4 weeks: when used in combination with disease-modifying anti-rheumatic drugs (DMARDS) or as monotherapy, the recommended starting dose is 4 mg/kg followed by an increase to 8 mg/kg based on clinical response. Doses exceeding 800 mg per infusion are not recommended. Actemra is supplied as an aqueous solution at a concentration of 20 mg/mL in three single-use vial sizes: 4 mL (80 mg); 10 mL (200 mg); and 20 mL (400 mg).

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, TOCILIZUMAB, 1 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #13
May 4, 2010

Attachment# 10.074

Topic/Issue:

Request to establish a code for Ustekinumab, trade name: STELARA™. Applicant's suggested language: Jxxxx Injection, Ustekinumab, 45 mg

Background/Discussion:

According to the Requester, STELARA™ (ustekinumab) is a human interleukin 12 and 23 antagonist indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Psoriasis is a chronic, immune-mediated disease, characterized by inflammation in the skin and the overproduction of skin cells, resulting in their accumulation the surface of the skin, which causes red, scaly plagues that may itch and bleed. STELARA™ (ustekinumab) is a new human monoclonal antibody with a novel mechanism of action that targets the cytokines interleukin-12 (IL-12) and interleukin-23 (IL-23). These cytokines are naturally occurring proteins that are important in the body's regulation of immune responses. The applicant also believes that they play an important role in psoriasis. STELARA™ is administered by subcutaneous injection. For patients weighing ≤100 kg, (220 lbs), the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. For patients weighing >100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks. In subjects weighing >100 kg, 45 mg was also shown to be efficacious. However, 90 mg resulted in greater efficacy in these subjects. STELARA™ (ustekinumab) is supplied as sterile solution of ustekinumab for subcutaneous administration in a single use vial containing 45 mg in 0.5 mL.

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, USTEKINUMAB, 1 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #14
May 4, 2010

Attachment# 10.071

Topic/Issue:

Request to establish a code for Romidepsin, trade name: Istodax®. Applicant's suggested language: "Romidepsin injection, 10 mg".

Background/Discussion:

According to the requester, Istodax® is a histone deacetylase (HDAC) inhibitor indicated for the treatment of cutaneous T-cell lymphoma in patients who have received at least one prior systemic therapy. HDACs catalyze the removal of acetyl groups from acetylated lysine residues in histones, resulting in the modulation of gene expression. HDACs also deacetylate non-histone proteins. Invitro, Romidepsin causes the accumulation of acetylated histones, and induces cell cycle arrest and apoptosis of some cancer cell lines with IC_{50} values in the nanomolar range. The recommended dose of Istodax® is 14 mg/m^2 administered intravenously over a 4-hour period on days 1, 8 and 15 of a 28-day cycle. Repeat cycles every 28 days provided that the patient continues to benefit from and tolerates the drug. Istodax® is supplied as a kit containing a single-use vial of lyophilized powder containing 10 mg of romidepsin and 10 mg of bulking agent (Povidone, USP) and a sterile diluent vial. According to the requester, there are no HCPCS codes to describe this product.

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, ROMIDEPSIN, 1 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #15
May 4, 2010

Attachment# 10.008

Topic/Issue:

Request to establish a new HCPCS code for Pralatrexate Injection, trade name: Folotyn™. Applicant's suggested language: "Jxxxx Pralatrexate, 1 mg"

Background/Discussion:

According to the requester, Folotyn™ is (Pralatrexate Injection) is an antineoplastic drug indicated for the treatment of relapsed or refractory peripheral T-cell lymphoma (PTCL). It is a folate analogue metabolic inhibitor that competitively inhibits dihydrofolate reductase. It is also a competitive inhibitor for polyglutamylation by the enzyme folylpolyglutamyl synthetase. This inhibition results in the depletion of thymidine and other biological molecules the synthesis of which depends on single carbon transfer. The recommended dosage of Folotyn™ is 30 mg/m2 *administered as an intravenous (IV) push* over 3-5 minutes via the side port of a free-flowing 0.9% sodium chloride injection, USP IV line once weekly for 6 weeks in 7-week cycles until progressive disease or unacceptable toxicity. It is supplied as a preservative-free aqueous parenteral solution contained in a single-use vial for intravenous administration. Each 1mL of solution contains 20 mg of pralatrexate, sufficient sodium chloride to achieve an isotonic solution and sufficient sodium hydroxide, and hydrochloric acid, if needed, to adjusts and maintain the pH at 7.5 - 8.5. Folotyn™ is supplied as either 20mg (1mL) or 40mg (2mL) single-use vials at a concentration of 20mg/mL. Any unused drug remaining after injection as well as any vials left at room temperature for more than 72 hours should be discarded. According to the requester, there are currently no HCPCS codes available to describe this product; no other drugs marketed under the same active ingredient; and no other drugs approved for the treatment of PTCL.

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, PRALATREXATE, 1MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #16
May 4, 2010

Attachment# 10.015

Topic/Issue:

Request to establish a code for Lacosamide, trade name: VIMPAT® injection. Applicant's suggested language: "Injection, lacosamide, 50 mg"

Background/Discussion:

According to the requester, VIMPAT® is an intravenous antiepileptic drug (AED) indicated as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older when oral administration is temporarily not feasible. The precise mechanism by which VIMPAT® injection exerts its antiepileptic effects is unknown. In vitro electrophysiological studies have shown that lacosamide selectively enhances slow inactivation of voltage-gated sodium channels, resulting in stabilization of hyperexcitable neuronal membranes and inhibition of repetitive neuronal firing. It is administered by intravenous infusion as follows: Partial onset seizures: 50 mg twice daily (100 mg/day). Additional dosing increments (100 mg 1 day given as two divided doses every week) may be given up to a maximum recommended daily dose of 200 to 400 mg/day. VIMPAT® may be given without further dilution, or mixed in compatible diluent, and should be administered intravenously over a period of 30 to 60 minutes. Switching from oral to intravenous dosing: the initial total daily intravenous dosage of VIMPAT® injection should be equivalent to the total daily dosage and frequency of oral VIMPAT® and should be infused intravenously over a period of 30 to 60 minutes. VIMPAT Injection (200 mg/20 mL) is supplied in single-use 20 mL vials, available in cartons of 10 vials. According to the requester, VIMPAT is a unique, single-source drug, and there is no existing HCPCS code to describe it.

CMS HCPCS Preliminary Decision:

Existing code C9254 INJECTION, LUCOSAMIDE, 1 MG adequately describes the product that is the subject of this request and is available for assignment by insurers if they deem appropriate.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision and asked the Workgroup to reconsider the request to establish a "J" code. The speaker indicated that non-Medicare payers, including Medicaid and private insurers, usually do not recognize HCPCS "C" codes in their claims processing systems. According to the speaker, there are similar drugs that are identified by "J" codes. The primary speaker stated that Medicaid is a significant payer for the epilepsy population.

HCPCS Public Meeting Agenda Item #17
May 4, 2010

Attachment# 10.025

Topic/Issue:

Request to establish a code for Olanzapine for extended release injectable suspension, trade name: Zyprexa® Relprevv™. Applicant's suggested language: "Injection, Olanzapine, long-acting, per 5 mg"

Background/Discussion:

According to the requester, Zyprexa® Relprevv™ is a long-acting injectable atypical antipsychotic agent indicated for the treatment of schizophrenia in adults. It is a physician-administered formulation of a currently marketed oral antipsychotic agent. It sustains the delivery of Olanzapine for a period of up to four weeks. Zyprexa® Relprevv™ is administered via a deep intramuscular gluteal injection. The dosing regimen is as follows:
10 mg/day with a recommended starting dose of 210 mg/2 weeks or 405 mg/4 weeks and a maintenance dose of 150 mg/2 weeks or 300mg/4 weeks;
15 mg/day with a recommended starting dose of 300 mg/2 weeks and a maintenance dose of 210 mg/2 weeks or 405 mg/4 weeks;
20 mg/day with a recommended starting dose of 300 mg/2 weeks and a maintenance dose of 300 mg/2 weeks. Maintenance doses are given after 2 months. Zyprexa® Relprevv™ is supplied in single-use convenience kits containing a 210 mg, 300 mg or 405 mg vial of Zyprexa and a 3-mL vial of sterile diluent. According to the requester, Risperdal Consta and Invega Sustenna are similar drugs that differ from Zyprexa in dosing. There are no head to head studies of these products to compare efficacy, effectiveness or safety. The current miscellaneous code J3490 does not allow complete patient access in the Medicaid population, and requires providers to supply additional documentation on claim forms which can generate payer/contractor claims processing delays and subsequent delays and even denials in provider payment if documentation requirements vary from payer to payer.

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, OLANZAPINE, LONG-ACTING, 1 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #18
May 4, 2010

Attachment# 10.016

Topic/Issue:

Request to establish a HCPCS code for Paliperidone Palmitate injection, extended release, trade name: Invega® Sustenna™. Applicant's suggested language: "Injection, Paliperidone Palmitate, extended release, 39 mg".

Background/Discussion:

According to the requester, Invega® Sustenna™ is an atypical antipsychotic agent indicated for acute and maintenance treatment of schizophrenia in adults. Invega® Sustenna™ is used to treat symptoms of schizophrenia and can be used to lessen the chance of schizophrenia symptoms from coming back. It is the first once-monthly, long-acting, injectable atypical antipsychotic approved in the U.S. for this use. It is intended for intramuscular use only. The active ingredient of Invega® Sustenna™ (Paliperidone Palmitate) is a psychotropic agent belonging to the chemical class of Benzisoxazole derivatives. Paliperidone Palmitate is hydrolyzed to paliperidone, the major active metabolite of risperidone. The mechanism of action of paliperidone is unknown, but is has been proposed that the drug's therapeutic activity in schizophrenia is mediated through a combination of central dopamine Type 2 (D_2) and serotonin Type 2 ($5HT_{2A}$) receptor antagonism. Invega® Sustenna™ is initiated with a dose of 234 mg on Treatment Day 1 and 156 mg one week later. The recommended monthly maintenance dose is 117 mg. Some patients may benefit from lower or higher maintenance doses within the recommended range of 39 to 234 mg based on individual patient tolerability and/or efficacy. Invega® Sustenna™ is an extended-release suspension available in prefilled syringes containing 39 mg, 78 mg, 117 mg, 156 mg, or 234 mg. The kit includes a pre-filled syringe and two safety needles. Administration should be in a single intramuscular injection and not divided injections. According to the requester, current codes do not describe this product. Risperdal Consta has the same active ingredient as Invega® Sustenna™ , however, it is an aqueous suspension using microsphere technology, and is administered every 2 weeks. Miscellaneous codes J3490 "UNCLASSIFIED DRUGS" and C9399 "UNCLASSIFIED DRUGS OR BIOLOGICALS" are inadequate because they do not permit appropriate identification of Invega® Sustenna™. A new, unique HCPCS code would facilitate patient access and allow payer systems to capture important product-specific data.

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, PALIPERIDONE PALMITATE, EXTENDED RELEASE, 1 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #19
May 4, 2010

Attachment# 10.036

Topic/Issue:

Request to establish a new code for OZURDEX™(dexamethasone intravitreal implant) 0.7mg. Applicant's recommended language: "Injection, dexamethasone, intravitreal implant, 0.7 mg".

Background/Discussion:

According to the requester, OZURDEX™ (dexamethasone intravitreal implant) is delivered solely by intravitreal injection. OZURDEX™ is indicated for the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO). Dexamethasone has been shown to suppress inflammation by inhibiting multiple inflammatory cytokines resulting in decreased edema, fibrin deposition, capillary leakage and migration of inflammatory cells. OZURDEX™ is a single intravitreal implant. It is packaged in a foil pouch with one single-use plastic applicator. Each applicator of dexamethasone intravitreal implant contains 0.7 mg dexamethasone preloaded into a single-use solid polymer drug delivery system NOVADUR™, to facilitate injection of the rod-shaped implant directly into the vitreous. This product is currently coded using new C9256 (Injection, dexamethasone intravitreal implant, 0.1 mg). The requester claims that codes J1094 (Injection, Dexamethasone Acetate, 1 mg) and J1100 (Injection, Dexamethasone Sodium Phosphate, 1 mg) are not appropriate for use because OZURDEX contains poly (D,L-lactide-co-glycolide) PLGA polymer matrix, and it is not Dexamethasone Acetate or Sodium Phosphate.

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, DEXAMETHASONE, INTRAVITREAL IMPLANT, 0.1 MG

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker agreed with the Workgroup's preliminary decision to establish a code for Ozurdex™ as well as the proposed code language and dosage descriptor. According to the requester, the pellet is not a divisible dose; there are no plans to market a lower dosage; and the existing "C" code for Ozurdex (which has a 0.1MG dosage) has not been problematic.

HCPCS Public Meeting Agenda Item #20
May 4, 2010

Attachment# 10.044

Topic/Issue:

Request to establish a Level II HCPCS J code for QUTENZA® (Capsaicin) 8% patch. Applicant's recommended language: "Capsaicin patch, 179 mg per 280 cm^2 patch".

Background/Discussion:

According to the requester, QUTENZA® (Capsaicin) 8% patch is indicated for the management of neuropathic pain associated with postherpetic neuralgia. Qutenza contains capsaicin in a localized dermal delivery system. The capsaicin in QUTENZA® is a synthetic equivalent of the naturally occurring compound (capsaicin) found in chili peppers. Only physicians or healthcare professionals under the close supervision of a physician are to administer Qutenza. Before, the patch is applied the painful area is pre-treated with a topical anesthetic. Each single-use QUTENZA® patch is 14 cm x 20 cm containing 179 mg of Capsaicin. The recommended dose is a single, 60-minute application of up to four patches. Treatment may be repeated every three months or as warranted by the return of the pain (not more frequently than every three months). Qutenza is supplied in a 1-patch carton and a 2-patch carton, each includes a 5 g tube of cleansing gel. According to the requester, Qutenza is a single-source drug not appropriately described by existing HCPCS codes, therefore a new code is warranted.

CMS HCPCS Preliminary Decision:

Establish Jxxxx CAPSAICIN PATCH, PER 10 SQUARE CENTIMETERS

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker agreed with the Workgroup's preliminary decision to establish a J code, but disagreed with the language descriptor. He recommended the inclusion of "8% capsaicin concentration" to the verbiage of the proposed code descriptor to distinguish this product from the over-the-counter (OTC) formulations of the drug. According to the requester, this concentration of capsaicin is 320 times more concentrated that the OTC versions. In addition, the speaker recommended that the dosage descriptor should be changed from "10 square centimeters" to "280 square centimeters" to identify a full patch rather than a portion of the patch, since most patients that will require this drug will use at least one patch.

HCPCS Public Meeting Agenda Item #21
May 4, 2010

Attachment# 10.066

Topic/Issue:

Request to establish a code for Methyl Aminolevulinate (MAL) cream 16.8%, trade name Metvixia® Cream 16.8%.

Background/Discussion:

According to the requester, Metvixia® Cream is the methyl ester of 5-aminolevulinate (ALA), used in photodynamic therapy (PDT) of Actinic Keratosis (AK). The standard treatment with Metvixia® in PDT is two treatments separated by one week, with follow up by a physician 3 months later. Dose is 1 gram per session. Metvixia® Cream is applied using a spatula about 1 mm thick layer to the lesions and 5 mm of surrounding normal tissue. the affected area is covered for three hours with an occlusive dressing enabling the active ingredient to be absorbed and produce photoactive porphyrins in tumor cells. Metvixia® Cream, 16.8% is supplied in 2 gram tubes packaged individually. According to the requester Metvixia® is a new drug with a unique chemical composition and action and there is no code to describe this product.

CMS HCPCS Preliminary Decision:

Establish Jxxxx METHYL AMINOLEVULINATE (MAL) FOR TOPICAL ADMINISTRATION, 16.8%, 10 MG

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker thanked the Workgroup for its preliminary decision to establish a code, but disagreed with the 10MG dosage descriptor. The speaker proposed a revision to the dosage descriptor from "10MG" to "2 GM". According to the speaker, 2 GM of Metvixia® Cream is applied over two treatment sessions at one week apart. Specifically, half of the tube (1 GM) is provided on day 1 and the remaining half of the tube is provided 7 days later.

HCPCS Public Meeting Agenda Item #22
May 4, 2010

Attachment# 10.070

Topic/Issue:

Request to establish a code for Telavancin, trade name: Vibativ™. Applicant's suggested language: "Injection, Telavancin, 10 mg".

Background/Discussion:

According to the requester, Vibativ is a rapidly bactericidal, injectable lipoglycopeptide antibiotic that inhibits the formation of the bacterial cell wall and disrupts bacterial cell membrane integrity. It is indicated for the treatment of patients with complicated skin and skin structure infections caused by susceptible strains of Gram-positive microorganisms. The recommended dosing of Vibativ for patients 18 years of age or older is 10 mg/kg administered over a 60-minute period by intravenous infusion once every 24 hours for 7 to 14 days. It is important to note that dosages of Vibativ may exceed 1,000 mg per day for patients whose weight exceeds 220 lbs. Vibativ is supplied in 250 mg and 750 mg single dose vials, in cartons of 10 vials. According to the requester, there is no current HCPCS code to describe Vibativ.

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, TELAVANCIN, 10 MG

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker supported the Workgroup's preliminary decision to establish a code for Vibativ™ as well as the proposed code language and dosage descriptor. The speaker urged CMS to finalize the HCPCS Workgroup's preliminary decision.

HCPCS Public Meeting Agenda Item #23
May 4, 2010

Attachment# 10.085

Topic/Issue:

Request to establish a code for Velaglucerase Alfa for injection, trade name: VPRIV™. Requester's suggested language: JXXXX, Velaglucerase Alfa injection, per unit.

Background/Discussion:

According to the Requester, VPRIV™ (Velaglucerase Alfa) is indicated for long-term enzyme replacement therapy (ERT) for pediatric and adult patients with type 1 Gaucher disease. VPRIV™ is designed to replace the missing enzyme, glucocerebrosidase. The recommended dose is 60 U/kg administered every other week as a 60-minute intravenous infusion. Dose adjustments can be made on an individual basis, based on achievement and maintenance of each patient's therapeutic goals. VPRIV™ is supplied as lyophilized powder (to be reconstituted and diluted for infusion), in individually packaged 200 U/vials and 400 U/vials. The benefit of a new, unique HCPCS code for this product is to facilitate patient access and allow payer systems to capture important product-specific data.

CMS HCPCS Preliminary Decision:

Establish Jxxxx INJECTION, VELAGLUCERASE ALFA, 100 UNITS

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #24
May 4, 2010

Attachment# 10.033

Topic/Issue:

Request to establish a Level II HCPCS J code to specifically describe aztreonam for inhalation solution, trade name: Cayston™. Applicant's recommended language: "aztreonam, inhalation solution, FDA-approved final product, non-compounded, unit dose form, administered through DME, per 75 mg.

Background/Discussion:

According to the requester, Aztreonam for inhalation solution is a monobactam antibacterial that exhibits activity in vitro against a broad spectrum of gram-negative aerobic pathogens including Pseudomonas Aeruginosa. It is indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with Pseudomonas Aeruginosa. Aztreonam for inhalation is cleared for use with the Altera® nebulizer system administered over a 2 to 3 minute period. The recommended dosage for both adults and pediatric patients 7 years of age and older is 75 mg, administered 3 times a day for a 28-day course, followed by 28 days off. Dosage is not based on weight or adjusted for age. Doses should be taken at least 4 hours apart. Cayston is supplied in kits containing 2 cartons each with a 14-day supply (42 vials of Aztreonam for inhalation solution 44 diluent ampules). The 4 additional diluent ampules in the kit are provided in case of spillage. According to the requester, there are currently no HCPCS codes that describe Aztreonam for Inhalation Solution. HCPCS code S0073 (Injection, Aztreonam, 500mg) applies to injectable Aztreonam formulated with Argenine, which is a different and distinct product. Chronic aerosol administration of Argenine to airways causes inflammation in patients with CF. In contrast, Cayston has been specifically formulated with the amino acid lysine, which has been shown to be well tolerated in the airways.

CMS HCPCS Preliminary Decision:

Establish Jxxxx AZTREONAM, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, 25 MG

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker supported the Workgroup's preliminary decision to establish a code but disagreed with the 25 MG dosage descriptor. The speaker proposed a revision to the dosage descriptor from "25 MG" to "75 MG" because the recommended dose for single-use is 75 MG. The speaker further stated that the adoption of the 75 MG dosage descriptor is appropriate since there are no other vial sizes available, and the dosage cannot be split, and is not based on weight or adjusted for age.

HCPCS Public Meeting Agenda Item# 25
May 4, 2010

Attachment# **10.005A**

Topic/Issue:

Request to establish 3 "J" codes: 1 for the Tyvaso Inhalation System Starter Kit, 1 for the Tyvaso Inhalation System Refill Kit, and 1 for the 4-pack short-term refill kit. Applicant's suggested language:
XXXX1 "Treprostinil, inhalation solution, 48.72 mg, with inhalation systems and accessories;"
XXXX2 "Treprostinil, inhalation solution, 48.72 mg, with accessories;"
XXXX3 "Treprostinil, inhalation solution, 6.96 mg"

Note: The Treprostinil (Tyvaso) drug component of this application is discussed in Request #10.005A, and the preliminary coding decision for the drug appears in this agenda. The Optineb-ir nebulizer and accessories component of this application is discussed in Request #10.005B. The preliminary decision that correlates with Request #10.005B will be posted in the June 8, 2010 Durable Medical Equipment (DME) HCPCS Public Meeting Agenda.

Background/Discussion:

According to the requester, Tyvaso (treprostinil) inhalation solution is a prostacyclin analogue indicated for the treatment of pulmonary arterial hypertension (WHO Group I) in patients with NYHA Class III symptoms, to increase walk distance. The major pharmacologic actions of treprostinil are direct vasodilation of pulmonary and systemic arterial vascular beds and inhibition of platelet aggregation. Initial dosage of Tyvaso is 3 breaths (6 mcg of treprostinil delivered per breath) per treatment session, with the dose increasing by an additional 3 breaths at approximately 1-2 week intervals up to the target maintenance dosage of 9 breaths per treatment session as tolerated.
Treprostinil inhalation solution is cleared by the FDA in combination with the Tyvaso inhalation system Optineb-ir Model On-100/7, an ultrasonic, pulsed-delivery inhalation system. Treprostinil is administered in four separate treatment sessions each day. Only one ampule of treprostinil is required to deliver the four daily treatment sessions. Treprostinil inhalation solution is supplied in 2.9 ml ampules, packaged as four ampules in a foil pouch. Each 2.9 mL contains 1.74 mg treprostinil (a concentration of 0.6 mg/ml).

Tyvaso is supplied as three different products:

NDC 66302-206-01: Tyvaso inhalation system starter kit, which contains a carton of 28 ampules (1 month supply) of treprostinil; two Tyvaso inhalation systems (the second system provides back-up capacity); and disposable supplies [(1) Tyvaso inhalation system instruction manual, (1) tyvaso inhalation system warranty card, [((2) sets of dome assembly, inhalation piece, mouthpiece, and 2 filter shells), (32) medicine cups, (65) filters, (1) measuring cup, (1)

nose clip, (2) plugs for storage between treatments, (2) AC wall plugs, (1) rechargeable battery, (1) 12V DC car adaptor, (1) storage box, (1) carrying case.]

NDC 66302-206-02: Tyvaso inhalation system refill kit, which contains a carton of 28 ampules (1 month supply) of treprostinil and disposable supplies [((1) set of dome assembly, inhalation piece, mouthpiece, and 2 filter shells), (32) medicine cups, (65) filters, (2) plugs for storage between treatment sessions.]

NDC 66302-206-03: A 4-pack short-term refill kit that contains four ampules of treprostinil that is intended for inpatient use.

According to the requester, the Optineb-ir Model ON-100/7, is an ultrasonic, pulsed-delivery inhalation system device intended for single patient use in the administration of Treprostinil for inhalation. The Optineb-ir operates ultrasonically by energizing a piezoelectric transducer at 2.4 MHz. This action collimates distilled water stored in the water reservoir ergizing liquid medicine stored in the medicine cup creating an aerosol above the liquid medicine and appears as a cloud. The proprietary dome (with baffle) is designed to control the size of the particles that are emitted from the device. The Optineb's software controls the aerolization process to occur during expiration and then responds by providing visual and audible signals to the patient requiring the patient to inhale the vapor. Optineb-ir is available only as a part of the Tyvaso Inhalation System Starter Kit and is not sold separately. The starter kit contains two nebulizers, one of which is a back-up n case nebulizer #1 fails or breaks. Depending on the source of a problem, it may be replaced under warranty. Replacement nebulizers not under warranty can only be obtained by purchasing a Tyvaso starter kit. Optineb-ir is designed for repeated uses for up to two years. According to the requester, use of the Optineb-ir with other products is unknown since this device has not been studied with other drugs. As such, use of Optineb-ir Model ON-100/7 with a drug other than treprostinil would be an off-label use.

According to the requester, nebulizers described by HCPCS codes E0570 NEBULIZER, WITH COMPRESSOR, E0580 NEBULIZER, DURABLE, GLASS OR AUTOCLAVABLE PLASTIC, BOTTLE TYPE, FOR USE WITH REGULATOR OR FLOWMETER and E0585 NEBULIZER, WITH COMPRESSOR AND HEATER are not ultrasonic nebulizers and therefore do not describe the Optineb-ir Model ON-100/7 nebulizer. HCPCS codes E0574 ULTRASONIC/ELECTRONIC AEROSOL GENERATOR WITH SMALL VOLUME NEBULIZER and E0575 NEBULIZER, ULTRASONIC, LARGE VOLUME, although described as ultrasonic nebulizers, are not "controlled dose inhalation delivery systems" (K0730). The Optineb ir uses a baffle plate to determine the particle size of the aerosol. The design that includes the baffle inside a dome is unique to the Optineb-ir Model ON 100/7, and makes this system different from other controlled dose inhalers coded at K0730. While traditional nebulizers generate droplets in a wide range of sizes, the Optineb technology generates droplets that are "monodisperse" and the particles are almost all the same size. There are no specific HCPCS codes for the three Tyvaso products.

CMS HCPCS Preliminary Decision:

1) Establish Jxxxx TREPROSTINIL, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, 1.74MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item. Written comments were submitted by the applicant in full support of the preliminary coding decision.

PAYMENT FOR PART B DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Background

Medicare Part B currently covers a limited number of prescription drugs. For the purpose of this discussion, the term “drugs” will hereafter refer to both drugs and biologicals. Currently, covered Medicare Part B drugs generally fall into three categories:

- Drugs furnished incident-to a physician's service - Injectable or intravenous drugs as well as non-injectable or non-intravenous drugs are administered incident-to a physician's service. Under the “incident-to” provision, the physician must incur a cost for the drug, and must bill for it. “Incident-to” coverage is limited to drugs that are not usually self-administered;
- Drugs administered via a covered item of durable medical equipment - DME drugs are administered through a covered item of DME, such as a nebulizer or pump; and
- Drugs covered by statute - Drugs specifically covered by statute include immunosuppressive drugs; hemophilia blood clotting factor; certain oral anti-cancer drugs; oral anti-emetic drugs; pneumococcal, influenza and hepatitis B vaccines; antigens; erythropoietin for trained home dialysis

patients; certain other drugs separately billed by end-stage renal disease (ESRD) facilities; and osteoporosis drugs.

Drugs Paid on a Cost or Prospective Payment Basis

Drugs paid on a cost or prospective payment basis that are outside of the scope of the current drug payment methodology include--drugs furnished during an inpatient hospital stay (except clotting factor); drugs paid under the outpatient prospective payment system (OPPS); drugs furnished by ESRD facilities whose payments are included in Medicare's composite rate; and drugs furnished by critical access hospitals, skilled nursing facilities (unless outside of a covered stay), comprehensive outpatient rehabilitation facilities, rural health facilities, and federally qualified health centers.

Part B Drug Payment Methodology

Historical Payment Methodology

Prior to January 1, 2004, payment for the majority of Medicare Part B drugs was set at 95 percent of the average wholesale price. The statutory term, average wholesale price (AWP), was not defined in law or regulation. In creating payment limits for Medicare covered drugs, Medicare relied on the list AWP which referred to the AWP published in commercial drug compendia such as Red Book, Price Alert, and Medispan.

In 2004, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) revised the drug payment methodology, reducing the payment rate for most covered Part B drugs from 95 percent of the AWP to 85 percent of the AWP.

Current Methodology

In 2005, the MMA again revised the drug payment methodology by creating a new pricing system based on a drug's Average Sales Price (ASP). Effective January 2005, Medicare pays for the majority of Part B covered drugs using a drug payment methodology based on the ASP. In accordance with section 1847A of the Social Security Act, manufacturers submit to us the ASP data for their products. These data include the manufacturer's total sales (in dollars) and number of units of a drug to all purchasers in the United States in a calendar quarter (excluding certain sales exempted by statute), with limited exceptions. The sales price is net of discounts such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927 of the Act). The Medicare payment rate is based on 106 percent of the ASP (or for single source drugs, 106 percent of wholesale acquisition cost (WAC), if lower), less applicable deductible and coinsurance. The WAC is defined, with respect to a drug or biological, as the manufacturer's list price for the drug or biological to wholesalers or direct

purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

After carefully examining Section 1847A of the Social Security Act, as established in the MMA, CMS has been reviewing its coding and pricing determinations to ensure that separate and appropriate payment is made for single source drugs and biologics as required by this section of the Act. In order to facilitate separate and appropriate payment, it may be necessary to create unique HCPCS level II codes for certain products. As part of this effort, we are also closely reviewing how we operationalize the terms 'single source drug,' 'multiple source drug,' and 'biological product' in the context of payment under section 1847A to identify the potential need to make any changes to our assignment of National Drug Codes to billing codes for payment purposes.

So that we can implement coding and pricing changes swiftly, CMS has used and will continue to use its internal process, when appropriate, for modifying the code set. Please be aware that internally generated code requests are not part of the HCPCs public meeting process.

Exceptions to ASP pricing methodology

The MMA exempted certain drugs from the ASP pricing methodology and payment for these drugs remained at 95 percent of the AWP. These drugs include:

- Vaccines – Influenza, Pneumococcal, Hepatitis B;
- Infusion drugs furnished through DME; and
- Blood and blood products (other than blood clotting factor)

Payment for Radiopharmaceuticals

The payment methodology for radiopharmaceuticals did not change under the MMA. Specifically, Section 303(h) states that "[n]othing in the amendments . . . shall be construed as changing the payment methodology . . . for radiopharmaceuticals . . ."

Dispensing/Supplying/Furnishing Fees

Dispensing Fees

Currently, Medicare pays an initial dispensing fee of $57.00 to a pharmacy for the initial 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time. This dispensing fee is a one-time fee applicable only to beneficiaries who are using inhalation drugs for the first time as Medicare beneficiaries.

Medicare also pays a dispensing fee of $33.00 to a pharmacy for a 30-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time. This dispensing fee will be paid for a 30-day period of inhalation drugs, except in those circumstances where an initial 30-day dispensing fee is applicable instead.

The pharmacy will also receive a dispensing fee of $66.00 for each dispensed 90-day period of inhalation drugs furnished through DME regardless of the number of shipments or drugs dispensed during that time and regardless of the number of pharmacies used by a beneficiary during that time.

Supplying Fees

For 2005, Medicare provided a supplying fee of $24 to a pharmacy for each supplied prescription of immunosuppressive drugs, oral anti-cancer drugs and oral anti-emetic drugs used as part of an anti-cancer chemotherapeutic regimen. The pharmacy also received a supplying fee of $50 for the initial supplied prescription of the above-mentioned drugs during the 1st month following the beneficiary's transplant.

Currently, Medicare pays a supplying fee of $24.00 for the first prescription of immunosuppressive, oral anti-cancer, or oral anti-emetic drugs supplied to a beneficiary during a 30-day period. Each pharmacy that supplies the above-

mentioned drugs to a beneficiary during a 30-day period will be eligible for one $24 fee in that 30-day period. The pharmacy will be limited to one $24 fee per 30-day period even if the pharmacy supplies more than one category of the above-mentioned drugs (for example, an oral anti-cancer drug and an oral anti-emetic drug) to a beneficiary.

Additionally, Medicare pays a supplying fee of $16.00 to a pharmacy for each subsequent prescription, after the first one, of immunosuppressive, oral anti-cancer, or oral anti-emetic drugs supplied to a beneficiary during a 30-day period. Medicare pays the supplying fee for each prescription, including prescriptions for different strengths of the same drug supplied on the same day (for example, prescriptions for 100mg tablets and 5 mg tablets).

Furnishing Fees

In 2005, Medicare began a furnishing fee per unit of clotting factor to entities that furnish blood clotting factor unless the costs of furnishing the blood clotting factor are paid through another payment system. In each year, the prior year's fee is increased by the percentage increase in the consumer price index for medical care for the 12-month period ending June of the previous year. For calendar year 2010, this fee is $0.17 per unit.

Part B versus Part D

The implementation of Medicare Part D does not change Medicare Part B drug coverage in any way. Drugs that were covered by Medicare Part B prior to the implementation of Part D continue to be covered by Medicare Part B.

Please see the following Web links for additional information regarding Part versus Part D coverage:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/BvsDCoverage_07.27.05.pdf

http://www.cms.hhs.gov/Pharmacy/Downloads/partsbdcoverageissues.pdf