# Centers for Medicare & Medicaid Services (CMS)
# Healthcare Common Procedure Coding System (HCPCS)
# Public Meeting Summary Report
# Drugs, Biologicals, and Radiopharmaceuticals
# Tuesday, April 28, 2009

## Introduction and Overview

Approximately 89 people attended. The agenda included 24 items.

John Warren provided an overview of Medicare payment. The overview was provided as a written document and it is attached to this summary.

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

Prior to the Public Meetings, CMS HCPCS workgroup meets to review all HCPCS code applications and makes preliminary coding recommendations. CMS also makes preliminary recommendations regarding the applicable Medicare payment category and methodology that will be used to set a payment amount for the items on the agenda. The preliminary coding and payment recommendations are posted on the HCPCS world-wide web site at www.cms.hhs.gov/medhcpcsgeninfo, as part of the HCPCS public meeting agendas.

Following the public meetings, CMS HCPCS workgroup reconvenes, and considers all the input provided at the Public Meetings regarding its preliminary coding recommendations. CMS also reconsiders its Medicare payment 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.

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

The process for developing agendas and speaker lists for the public meetings, and Guidelines for Proceedings at CMS' Public Meetings are posted on the official HCPCS world wide web site at:
http://cms.hhs.gov/medhcpcsgeninfo/downloads/2008guidelines.pdf . The standard application format for requesting a modification to the HCPCS Level II Coding System, along with instructions for completion and background information regarding the HCPCS

Level II coding process is available at: http://cms.hhs.gov/medhcpcsgeninfo/downloads/2009_alpha.pdf. 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, April 28, 2009, 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 #09.002
Request to restore the original "per study dose" descriptor for code A9500, and delete "up to 40 millicuries."

No Primary Speaker

**AGENDA ITEM #2**
Attachment #09.028
Request to establish a code for Iobenguane I-123 (123-I meta-iodobenzylguanidine), trade name: AdreView.

No Primary Speaker

**AGENDA ITEM #3**
Attachment #09.094
Request to establish a code for Gadofosveset Trisodium, trade name: Vasovist (MS-325).

No Primary Speaker

**AGENDA ITEM #4**
Attachment #09.020
Request to establish a "J" code for gadoxetate disodium, trade name: EOVIST® Injection.

Primary Speaker: Sonali Padhi of Bayer HealthCare Pharmaceuticals

**AGENDA ITEM #5**
Attachment #09.037
Request to establish a code for Isosulfan blue, trade name: Lymphazurin 1% Blue Dye.

Primary Speaker: Charles Cox, M.D.

**AGENDA ITEM #6**
Attachment #09.006
Request to revise the unit dose descriptor for current HCPCS code J3473 "INJECTION, HYALURONIDASE, RECOMBINANT, 1 USP UNIT."

No Primary Speaker

**AGENDA ITEM #7**
Attachment #09.014
Request to establish a code for Pasteurized Human Fibrinogen Concentrate, trade name: Riastap(TM).

No Primary Speaker

**AGENDA ITEM #8**
Attachment #09.108
Request to establish a code for Palivizumab, trade name: Synagis.

No Primary Speaker

**AGENDA ITEM #9**
Attachment #09.036
Request to establish a code for Epoprostenol Sodium. Trade name: Epoprostenol for Injection (EFI)

Primary Speaker: Marnie Sharpe of Actelion Pharmaceuticals

**AGENDA ITEM #10**
Attachment #09.051
Request to establish a code for plerixafor, trade name: Mozobil.

Primary Speaker: Pritesh Gandhi, M.D.

**AGENDA ITEM #11**
Attachment #09.076
Request to establish a code for Degarelix for injection.

Primary Speaker: Henri Boodee, M.D.

**AGENDA ITEM #12**
Attachment #09.100
Request to establish a code for Temozolomide, trade name: Temodar(R) for injection.

Primary Speaker: Chip Bousum of Schering-Plough

**AGENDA ITEM #13**
Attachment #09.075
Request to establish a code for Triamcinolone Acetonide injection suspension 80 mg/mL, trade name: Trivaris(TM).

No Primary Speaker

**AGENDA ITEM #14**
Attachment #09.074
Request to revise code J0585 "BOTULINUM TOXIN TYPE A, PER UNIT", trade name: BOTOX.

No Primary Speaker

**AGENDA ITEM #15**
Attachment #09.085
Request to establish a new product-specific code for a polymeric surgical mesh, trade name: Permacol.

Primary Speaker: Dinakar Golla, M.D.

**AGENDA ITEM #16**
Attachment #09.033
Request to establish a code for reconstructive Tissue Matrix [LTM Surgical Mesh], trade name: Strattice®.

Primary Speaker: Navin Singh, M.D.

**AGENDA ITEM #17**
Attachment #09.047
Request to establish a code for Donated Human Tissue/Skin Allograft, trade name: AlloSkin.

No Primary Speaker

**AGENDA ITEM #18**
Attachment #09.072
Request to establish a new "J" code for Fibrin Sealant VH S/D 4 (human), trade name: ARTISS [Fibrin Sealant (Human)].

Primary Speaker: Janet Raciti of Baxter Healthcare

**AGENDA ITEM #19**
Attachment #09.022
Request to establish a "J" code for Antihemophilic Factor (Recombinant), Plasma/Albumin-Free. Trade name: XYNTHA.

No Primary Speaker

**AGENDA ITEM #20**
Attachment #09.027
Request to establish a code for C1 Inhibitor (Human) for Intravenous Use, Freeze-Dried Powder for Reconstitution, trade name: Cinryze.

Primary Speaker: Howard Levy of ViroPharma, Inc.

**AGENDA ITEM #21**
Attachment #09.023
Request to establish a code for romiplostim, trade name: Nplate.

Primary Speaker: Mahesh Krishnan, M.D.

**AGENDA ITEM #22**
Attachment #09.018
Request to establish a code for rilonacept, trade name: ARCALYST®.

No Primary Speaker

**AGENDA ITEM #23**
Attachment #09.073
Request to establish a new "J" code for Certolizumab Pegol, trade name: CIMZIA.

No Primary Speaker

**AGENDA ITEM #24**
Attachment #09.102
Request to revise the dose descriptor of existing code J7322 to facilitate accurate coding for Synvisc-ONE(TM).

Primary Speaker:  Chris Murray, M.D.

**HCPCS Public Meeting Agenda Item #1**
**April 28, 2009**

**Attachment: #09.002**

**Topic/Issue:**
Request to restore the original "per study dose" descriptor for code A9500, and delete "up to 40 millicuries." Applicant's suggested language: "Technetium Tc-99m Sestamibi, diagnostic, per study dose."

**Background/Discussion:**
According to the requester, the HCPCS descriptor for this radiopharmaceutical, reflecting "per dose" remained essentially intact for over 10 years. With the addition of "up to 40 millicuries" there has been confusion and inconsistency in provider billing and insurer policies. Returning to the original "per dose" descriptor will eliminate the confusion and promote more accurate and uniform billing for this radiopharmaceutical. Further, there is in 2008 a widespread support from the medical community, including the Society of Nuclear Medicine (which had initiated the request to add "up to 40 millicuries"), and the American College of Radiology to restore the original descriptor, consistent with changes proposed in CMS' preliminary decision published in Spring, 2008. Cardiolite (Technetium Tc99m Sestamibi) is a myocardial perfusion agent that is intended for detecting coronary artery disease by localizing myocardial ischemia and infarction, in evaluating myocardial function and developing information for use in patient management decisions. For myocardial imaging, the suggested dose range for IV administration is a single dose in the average patient (70 Kg) is 370-1110 MBq (10-30 mCi). For breast imaging, the recommended dose range for I.V. administration is a single dose of 740-1110 MBq (20-30 mCi).

**CMS HCPCS Preliminary Decision:**
Revise code A9500 which currently reads: "TECHNETIUM TC-99M SESTAMIBI, DIAGNOSTIC, PER STUDY DOSE, UP TO 40 MILLICURIES," to instead read: "TECHNETIUM TC-99M SESTAMIBI, DIAGNOSTIC, PER STUDY DOSE"

**Summary of Primary Speaker Comments at the Public Meeting:**
There was no primary speaker for this item.

**HCPCS Public Meeting Agenda Item #2**
**April 28, 2009**

**Attachment: #09.028**

**Topic/Issue:**
Request to establish a code for Iobenguane I-123 (123-I meta-iodobenzylguanidine), trade name: AdreView. Applicant's suggested language A95XX "lobenguane I-123 injection, per study dose"

**Background/Discussion:**
According to the requester, AdreView is a diagnostic radiopharmaceutical agent for gamma scintigraphy. It is indicated for use in the detection of primary or metastatic pheochromocytoma or neuroblastoma as an adjunct to other diagnostic tests. Iobenguane I-123 shows increased accumulation in tissues that can take up and retain norephinephrine and other related neurohormones. These include the liver, lungs, heart, spleen and salivary glands. The selective uptake mechanism allows detection and localization of specific neuroendocrine tumors and adrenal medullary hyperplasia. As an adjunct to other diagnostic tests, Iobenguane I-123 is administered intravenously to oncology patients for the evaluation of and localization of intra- and extra- adrenal pheochromocytomas, paragangliomas, neuroblastomas, and metastatic lesions from these tumors. The recommended dose is 10 mCi (370 MBq) for adults 16 years or older, or for pediatric patients under age 16 weighing 70 kg or more. For patients under 16 years of age and weighing less than 70 kg, the dose is calculated according to a table. AdreView is supplied in single-use vials containing 5 mL of sterile solution (2 mCi per mL) for intravenous injection.

**CMS HCPCS Preliminary Decision:**
Establish Axxxx Iodine I-123 IOBENGUANE, DIAGNOSTIC, PER MILLICURIE

**Summary of Primary Speaker Comments at the Public Meeting:**
There was no primary speaker for this item.

**HCPCS Public Meeting Agenda Item #3**
**April 28, 2009**

**Attachment: #09.094**

**Topic/Issue:**
Request to establish a code for Gadofosveset Trisodium, trade name: Vasovist (MS-325). Applicant's suggested language: "Injection, gadofosvest trisodium, per ml".

**Background/Discussion:**
According to the requester, Vasovist is a new gadolinium-based blood-pool contrast agent developed specifically for magnetic resonance angiography (MRA). Vasovist binds reversibly to albumin and remains in the circulation for an extended period of time, providing extended intravascular enhancement (steady-state imaging). MS-325 enhanced MRA requires a fraction of the dose of Gadolinium compared to that of non-blood pool specific Gadolinium based contrast agents used off-label for MRA. This product is administered intravenously by hand or power injector. Recommended adult patient dosage is 0.12 mL/kg of body weight. Because of its unique albumin bindings, MS-325 is retained in the blood stream allowing imaging of multiple vascular beds. Unlike other Gadolinium-based agents, there is no need for multiple administrations. Accordingly, there is no anticipated need for doses above 8.4 mL (for a 70 kg individual). Vasovist will be supplied in a vial or prefilled syringe and would typically be ordered in quantities such as a box of 10 (10 or 15 mL) vials. According to the requester, there is no other product on the market with the same active ingredient used in Vasovist, and existing MR contrast HCPCS codes do not adequately describe the chemical entity in Vasovist.

**CMS HCPCS Preliminary Decision:**
Establish Axxxx INJECTION, GADOFOSVESET TRISODIUM, 1 ML

**Summary of Primary Speaker Comments at the Public Meeting:**
There was no primary speaker for this item.

**HCPCS Public Meeting Agenda Item #4**
**April 28, 2009**

**Attachment: #09.020**

**Topic/Issue:**
Request to establish a "J" code for gadoxetate disodium, trade name: EOVIST® Injection. Applicant's suggested language: JXXXX "Injection, Gadoxetate Disodium (EOVIST), per 1 mL"

**Background/Discussion:**
According to the requester, EOVIST® injection is a unique gadolinium-based contrast agent and is the first organ-specific MRI contrast agent approved in the United States in more than a decade. EOVIST® is indicated for use in T1-weighted MRI of the liver to detect and characterize lesions in adults with known or suspected focal liver disease. EOVIST® is a paramagnetic contrast agent for MRI and contains the active pharmaceutical ingredient gadoxetate disodium. EOVIST® injection is for intravenous use only and should be administered undiluted intravenously as a single intravenous bolus injection at a flow rate of approximately 2 mL per second. EOVIST®, as a paramagnetic compound, develops a magnetic moment when placed in a magnetic field. EOVIST® produces a large magnetic moment that results in a local magnetic field, yielding enhanced relaxation rates of water protons in the vicinity of the paramagnetic agent. This leads to an increase in signal intensity of blood and tissue. The recommended dose is 0.1 mL/kg body weight (0.025 mmol/kg body weight). EOVIST® is supplied in single-use 10 mL vials of ready-to-use aqueous solution. Each mL contains 181.43 mg Gadoxetate Disodium (equivalent to 0.25 mol/L) for intravenous use only. According to the applicant, a permanent code will facilitate claims processing and tracking of EOVIST®, and would be "consistent with CMS' instructions to hospitals to bill specific drugs whether or not the product is packaged into an Ambulatory Payment Classification (APC)." The applicant is specifically seeking a "J" code, since EOVIST® has an NDA approval. The applicant indicated that EOVIST® is a "single-source" drug.

**CMS HCPCS Preliminary Decision:**
Establish Axxxx INJECTION, GADOXETATE DISODIUM, 1ML

**Summary of Primary Speaker Comments at the Public Meeting:**
The primary speaker agreed with the workgroup's preliminary decision to establish a code, but requested a "J" code (as opposed to an "A" code) because insurers are more likely to bundle payment (e.g., not pay separately for the product), when an "A" code is used.

**HCPCS Public Meeting Agenda Item #5**
**April 28, 2009**

**Attachment: #09.037**

**Topic/Issue:**
Request to establish a code for Isosulfan blue, trade name: Lymphazurin 1% Blue Dye. Applicant's suggested language: "LYMPHAZURIN (ISOFULFAN BLUE) INJECTION, DIAGNOSTIC, UP TO 5 ML)

**Background/Discussion:**
According to the requester, Lymphazurin is a dye used to delineate lymphatic vessels draining the region of its injection (lymphatic mapping). It is most often used in identifying the sentinel lymph node (SNL), the hypothetical first lymph node reached by metastasizing cancer cells from a neoplasm or tumor. SNL identification and biopsy is mostly used in melanoma and breast cancer and reliably determines nodal status in greater than 95% of breast cancer patients tested. Lymphazurin is also used as an adjunct to lymphography in: primary and secondary lymphedema of the extremities; chyluria, chylous ascites, chylothorax, detection of lymphatic fistulas secondary to surgical or iatrogenic disruption of lymph channels; lymph node involvement of primary or secondary neoplasm; and lymph node response to therapeutic modalities. Lymphazurin is a diagnostic contrast agent that is administered by injection. Lymphazurin is supplied as a 5.0 ml single dose vial. Each mL of solution contains 10 mg Isosulfan Blue, 6.6mg Sodium Monohydrogen Phosphate and 2.7mg Dihydrogen Phosphate as buffering agents. According to the applicant, there is not "supporting material" indicating that Lymphazurin can be used with existing code A9535 "Injection, Methylene Blue, 1 ML" or A9451 "Technetium TC-99M Sulfur Colloid, Diagnostic, per study dose, up to 20 millicuries" and no specific HCPCS codes exist that "adequately describe and are supported by clinical evidence" for uses of Lymphazurin.

**CMS HCPCS Preliminary Decision:**
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For HOPPS, this product is packaged into the procedure it is reported with.

**Summary of Primary Speaker Comments at the Public Meeting:**
The primary speaker disagreed with the workgroup's preliminary decision, stating that a code is needed so that insurers will pay for this product. The speaker also stated that the code for Methylene Blue is often used to bill this product and there is not a way to track utilization of this specific product, or identify which product was used (e.g., when an adverse event occurs), and the products are not interchangeable. The speaker requested a unique code for Isosulfan Blue, and claimed that this product meets the criteria under 1847A for separate payment as a single-source drug.

**HCPCS Public Meeting Agenda Item #6**
**April 28, 2009**

**Attachment: #09.006**

**Topic/Issue:**
Request to revise the unit dose descriptor for current HCPCS code J3473 "INJECTION, HYALURONIDASE, RECOMBINANT, 1 USP UNIT." Applicant's suggested language: "Injection, hyaluronidase, recombinant, up to 150 USP units"

**Background/Discussion:**
Hylenex is a purified preparation of the enzyme recombinant human hyaluronidase. It is indicated as an adjuvant to increase the absorption and dispersion of other injected drugs; for subcutaneous fluid administration; and as an adjunct in subcutaneous urography for improving resorption of radiopaque agents. According to the requester, Hylenex is the only recombinant human hyaluronidase product currently available, and is the only product currently assigned to code J3473. The applicant believes that the nomenclature of code J3473 appropriately describes Hylenex, but states that an analysis of Medicare hospital outpatient claims data suggests that the unit descriptor has resulted in incorrect billing. Hylenex is supplied sterile as 150-USP-units per mL in a single-use 2 mL vial. 1 mL single dose vials are available in boxes of 4. Based on clinical practice and Medicare's wastage policy, J3473 should rarely be billed in increments of less than 150 units. However, in the 2009 proposed rule version of Medicare Hospital Outpatient Prospective Payment System Limited Data Set, 36 percent of J3473 line items were incorrectly billed as 1 unit. According to the requester, a revised dosage of "up to 150 USP units" would minimize billing errors by reflecting more accurately the actual dosage of Hylenex administered. It would also be consistent with the dose descriptor for non-ovine, non-recombinant hyaluronidase HCPCS code J3470.

**CMS HCPCS Preliminary Decision:**
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector to revise the dosage descriptor of this code. Existing code J3473 "INJECTION, HYALURONIDASE, RECOMBINANT, 1 USP UNIT" adequately describes the product that is the subject of this request. To help avoid billing errors and ensure that the units of drugs administered to patients are accurately reported, it is important that the complete long descriptors for the applicable codes are reviewed prior to submitting a claim.

**Summary of Primary Speaker Comments at the Public Meeting:**
There was no primary speaker for this item.

**HCPCS Public Meeting Agenda Item #7**
**April 28, 2009**

**Attachment: #09.014**

**Topic/Issue:**
Request to establish a code for Pasteurized Human Fibrinogen Concentrate, trade name: Riastap(TM). Applicant's suggested language: "Human Fibrinogen Concentrate, Pasteurized Riastap(TM), 100 mg each billable unit.

**Background/Discussion:**
According to the requester, Riastap obtained Orphan Drug designation in March 2008 and will be the first and only FDA approved fibrinogen concentrate. Riastap is a highly purified, lyophilized fibrinogen (coagulation Factor I) manufactured from large pools of human plasma. It is supplied in single use only vials containing approximately 1000 milligrams of fibrinogen. It is indicated for patients with Congenital Fibrinogen Deficiency. It replaces missing, low, or malfunctioning coagulation factor, necessary to form a blood clot. Following reconstitution with 50 ml sterile water, Riastap will contain 900 to 1300 mg fibrinogen. The fibrinogen potency for each lot is printed on the vial label. The initial dose for Riastap is 70 mg per kg of body weight, administered intravenously through a dedicated administration line. The injection rate should not exceed 5ml per minute. Any additional doses will be determined by the severity of the injury or bleeding event; and the baseline fibrinogen levels of the individual patient. Riastap contains no preservatives and any unused portion is to be discarded. Riastap is supplied as a lyophilized powder. Sodium hydroxide and hydrochloric acid may be used to adjust the pH.

**CMS HCPCS Preliminary Decision:**
Establish Jxxxx HUMAN FIBRINOGEN CONCENTRATE, 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 edit the language of the proposed new code to read as follows: “Injection, Fibrinogen Concentrate (Human), RiaSTAP™, 100mg.”

**HCPCS Public Meeting Agenda Item #8**
**April 28, 2009**

**Attachment: #09.108**

**Topic/Issue:**
Request to establish a code for Palivizumab, trade name: Synagis.

**Background/Discussion:**
According to the requester, Synagis is a humanized monoclonal antibody produced by recombinant DNA technology, directed to an epitope in the A antigenic sited of the F protein of respiratory syncytial virus (RSV). Synagis is used to help prevent respiratory syncytial virus (RSV), the leading cause of upper respiratory disease in pre-term infants. Synagis is a composite of human and murine antibody sequences. It is supplied as a sterile, preservative-free liquid solution at 100 mg/mL to be administered by intramuscular injection. Each 100 mg single-dose vial of Synagis liquid solution contains 100 mg of Synagis, 3.9 mg of histidine, 0.1 mg of glycine, and 0.5 mg of chloride in a volume of 1 mL. Each 50 mg single-dose vial of Synagis liquid solution contains 50 mg of Synagis, 1.9 mg of histidine, 0.06 mg of glycine, and 0.2 mg of chloride in a volume of 0.5 mL. According to the requester, there are no similar products on the market and existing CPT codes do not adequately describe this product.

**CMS HCPCS Preliminary Decision:**
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. Contact the American Medical Association (AMA) for CPT coding guidance.

**Summary of Primary Speaker Comments at the Public Meeting:**
There was no primary speaker for this item.

**HCPCS Public Meeting Agenda Item #9**
**April 28, 2009**

**Attachment: #09.036**

**Topic/Issue:**
Request to establish a code for Epoprostenol Sodium. Trade name: Epoprostenol for Injection (EFI)

**Background/Discussion:**
According to the requester, Epoprostenol for Injection (EFI) is indicated for long-term intravenous (IV) 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. EFI has two main pharmacological actions: (1) direct vasodilation of pulmonary and systemic arterial vascular beds, and (2) inhibition of platelet aggregation. EFI offers significant advantages that stem from its unique formulation. While existing products use a glycine-based buffer and must be reconstituted with proprietary diluent, finished EFI is formulated with arginine. As a result, the finished product can be reconstituted with readily-available, non-proprietary diluents, and the fully diluted product has a higher pH than previously approved products. These distinctions ensure EFI's stability at room temperature and under refrigeration for longer periods than existing products. Thus, EFI is easier to reconstitute, store, dilute, and administer-and, in emergencies, may be a more dependable treatment-than existing products, and may be less wasteful than existing products. In addition, EFI has proven antimicrobial properties that may help minimize the risk of sepsis. Existing codes for injectable epoprostenol products, however, do not cover the dosage strength, unique formulation, or full cost of EFI. Epoprostenol is administered by continuous intravenous infusion via central venous catheter using an ambulatory infusion pump. During initiation of treatment, temporary peripheral IV infusion may be used. Chronic infusion should be initiated at 2 ng/kg per minute and increased in increments of 2 ng/kg every 15 minutes or longer until dose limiting effects are elicited or a tolerance limit is established. Epoprostenol for Injections is supplied as lyophilized material in 10 mL vials, each containing Epoprostenol Sodium equivalent to 1.5 mg (1,500,000 ng) Epoprostenol. According to the applicant, existing code J1325 "Injection, Epoprostenol, 0.5 MG" does not adequately describe EFI for the following reasons: (1) Since EFI is only available in 1.5 mg vials, it "falls outside the terms of code J1325"; (2) because EFI does not require the use of a proprietary diluent, code S0155 "Sterile Dilutant for Epoprostenol, 50ML" cannot be used together with code J1325 as it can with Flolan and generic Flolan. Therefore, while Flolan and generic Flolan can combine the 2 codes to obtain full reimbursement, providers who dispense EFI cannot; (3) EFI is a "single-source" drug and therefore a unique HCPCS code is warranted.

**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:**

The primary speaker disagreed with the workgroup's preliminary decision. The speaker stated that Epoprostenol for Injection (EFI) is an orphan drug; that the FDA has determined that EFI has not therapeutic equivalents; and that the first date of sale was after October 1, 2003. The speaker claimed that EFI meets the requirements for "coding" as a "single-source drug". The speaker requested that CMS reconsider its decision on the basis of Section 1847(A) of the Act.

**HCPCS Public Meeting Agenda Item #10**
**April 28, 2009**

**Attachment: #09.051**

**Topic/Issue:**
Request to establish a code for plerixafor, trade name: Mozobil. Applicant's suggested language "Plerixafor, for injection, per 1 mg"

**Background/Discussion:**
According to the requester, plerixafor (Mozobil) is the first and only selective antagonist of the CXCR4 chemokine receptor. Mozobil is used in conjunction with granulocyte colony-stimulating factor (G-CSF) to mobilize hematopoetic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkins lymphoma (NHL) and multiple Myeloma (MM). Mozobil was granted orphan drug designation by the FDA in July 2003. The recommended dose of Mozobil is 0.24 mg/kg body weight by subcutaneous (SC) injection. Mozobil should be administered approximately 11 hours prior to initiation of apheresis. It is supplied in single-use 2mL vials containing 1.2 mL of 20mg/mL solution.

**CMS HCPCS Preliminary Decision:**
Establish Jxxxx INJECTION, PLERIXAFOR, 1 MG

**Summary of Primary Speaker Comments at the Public Meeting:**
The primary speaker supported the workgroup's preliminary decision to establish a code for Plerixafor and the proposed code language and dose descriptor. He stated that a unique Level II HCPCS code will allow providers and payers to submit and pay for claims appropriately for use of this product.

**HCPCS Public Meeting Agenda Item #11**
**April 28, 2009**

**Attachment: #09.076**

**Topic/Issue:**
Request to establish a code for Degarelix for injection (approved trade name not supplied). Applicant's suggested language: "Degarelix injection - 80 mg".

**Background/Discussion:**
According to the requester, Degarelix is a GnRH receptor antagonist indicated for the treatment of patients with advanced prostate cancer. It blocks GnRH from the hypothalamus from binding to the GnRH receptors, preventing the release of luteinizing hormone from the pituitary. Degarelix achieves rapid and sustained suppression of testosterone, which drops to castration levels in over 95% of patients by day three of treatment. It is administered by deep subcutaneous injection under the abdominal skin. Degarelix requires a loading dose of 240 mg, given as two injections of 120 mg. Monthly maintenance doses are 80 mg, given as one subcutaneous injection. Degarelix is supplied as a starting does containing 2 vials of 120 mg powder for injection and a maintenance dose containing 1 vial of 80 mg powder for injection. The applicant states that Degarelix is a single source drug for the purpose of payment under Section 1847A of the Social Security Act, and suggests that a unique HCPCS code is needed to facilitate separate payment.

**CMS HCPCS Preliminary Decision:**
Establish Jxxxx INJECTION, DEGARELIX, 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, but disagreed with the 1MG dose descriptor. The speaker proposed a revision to the dosage descriptor from "1MG " to "80MG". According to the speaker, this change will avoid inadvertent inference that Degarelix can be used at varying dosages other than the 240MG and 80MG starting and maintenance dosages. The speaker also requested assignment of a "J" code in the 9000 series to facilitate correct payment as a hormonal anti-neoplastic agent to be billed with CPT code 96402 for the injection procedure.

**HCPCS Public Meeting Agenda Item #12**
**April 28, 2009**

**Attachment: #09.100**

**Topic/Issue:**
Request to establish a code for Temozolomide, trade name: Temodar(R) for injection. Applicant's suggested language: "Injection, Temozolomide for intravenous infusion, per 5 mg".

**Background/Discussion:**
According to the requester, Temodar is indicated for the treatment of adult patients with newly diagnosed glioblastoma multiforme (GBM) used concomitantly with radiotherapy and then as maintenance treatment. It is also indicated for refractory anaplastic astrocytoma. Temodar is infused intravenously via a pump over a period of 90 minutes. Dosage is based on a patient's body surface area (BSA) and disease state, and as such, is highly variable. For newly diagnosed GBM: 75 mg/m squared of Temodar for 42 days followed by initial maintenance dose of 150 mg/m squared once daily for days 1-5 of a 28 day cycle for 6 cycles. For Refractory Anaplastic Astrocytoma: Initial dose 150 mg/m squared Temodar once daily for 5 consecutive days per 28 day treatment cycle. Temodar is supplied as a lyophilized powder in single-use vials containing 100 mg temozolomide each. According to the requester, Temodar is not described by any existing HCPCS Level II codes because it is "a unique, single-source, intravenously delivered drug."

**CMS HCPCS Preliminary Decision:**
Establish Jxxxx Injection, Temozolomide, 1mg.

**Summary of Primary Speaker Comments at the Public Meeting:**
The primary speaker supported the workgroup's preliminary decision to establish a code for Temodar for injection as well as the proposed code language and dose descriptor. The speaker suggested that this decision be finalized.

**HCPCS Public Meeting Agenda Item #13**
**April 28, 2009**

**Attachment: #09.075**

**Topic/Issue:**
Request to establish a code for Triamcinolone Acetonide injection suspension 80 mg/mL, trade name: Trivaris(TM). Applicant's suggested language: "Injection, Triamcinolone Acetonide, sterile aqueous gel suspension with sodium hyaluronate, preservative free, prefilled syringe, 8 mg".

**Background/Discussion:**
According to the requestor, Trivaris 80 mg/mL is a synthetic glucocorticoid with anti-inflammatory action. Trivaris acts on the immune system to block the substances that trigger allergic and inflammatory response. It was specifically formulated for intravitreal use and is indicated for the treatment of sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids. Trivaris can also be used for a range of disorders that require intramuscular or intra-articular injection. The dominant use is expected to be intravitreal injection. When injected intravitreally, the usual dosage is a single injection of 4 mg per 0.05 mL. When administered intra-articularly or intramuscularly, the initial dose may vary from 2.5 mg to 100 mg per day depending on the specific disease being treated. Trivaris is packaged in single-use syringes of sterile aqueous gel suspension containing 8 mg of triamcinolone acetonide in 0.1 mL in a vehicle containing by weight percents of 2.3% sodium hyaluronate; 0.63% sodium chloride; 0.3% sodium phosphate, dibasic; 0.04% sodium phosphate, monobasic; and water for injection. According to the requester, Trivaris is not therapeutically equivalent to any other triamcinolone acetonide product.

**CMS HCPCS Preliminary Decision:**
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to consider this request until such time as this product is marketed in the U.S.

**Summary of Primary Speaker Comments at the Public Meeting:**
There was no primary speaker for this item.

**HCPCS Public Meeting Agenda Item #14**
**April 28, 2009**

**Attachment: #09.074**

**Topic/Issue:**
Request to revise code J0585 "BOTULINUM TOXIN TYPE A, PER UNIT", trade name: BOTOX. The applicant recommends that the descriptor instead read "_____ botulinumtoxinA, per unit" (unique prefix to be provided once approved by the FDA).

**Background/Discussion:**
According to the applicant, introduction of other serotype A Botulinum toxins is anticipated beginning in 2009. Since "no two Botulinum toxin biologics are interchangeable" and "units of one type A serotype biologic are non-standard and therefore not interchangeable with units of another type A serotype", distinct generic names should be used in order to avoid confusion, and the language of J0585 should be revised accordingly. Although FDA-approved biologics are exempt from compliance with "overlap select agents and toxins" as regulated by HHS and the Department of Agriculture, the applicant believes there is a remaining need to distinguish these agents in order to be able to track them for "biodefense purposes". And finally, the applicant believes BOTOX should be distinguished from other serotype A Botulinum toxins because it meets the single souce biological criteria under Section 1847A of the Social Security Act. The applicant states that the FDA has approved "_____ Botulinum toxin A" as the" stem nomenclature for all seroytpe A Botulinum toxin biologics," and that a generic name (filling in the prefix before the stem) is expected to be approved in early 2009. The applicant recommends use of unique generic prefixes together with the Botulinum toxin A stem as a nomenclature convention for HCPCS Level II codes for Botulinum toxin type A products. Botox is supplied in single-use vials containing 100 [Allergan] Units of Clostridium Botulinum type A neurotoxin complex. Dosing is individualized to the patient and use.

**CMS HCPCS Preliminary Decision:**
Existing code J0585 “BOTULINUM TOXIN TYPE A, PER UNIT” 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 #15**
**April 28, 2009**

**Attachment: #09.085**

**Topic/Issue:**
Request to establish a new product-specific code for a polymeric surgical mesh, trade name: Permacol. Applicant's suggested language: "Dermal (substitute) collagen tissue of non-human origin, with or without other bioengineered or processed elements, without metabolically active elements (Permacol), per sq. cm."

**Background/Discussion:**
According to the requester, Permacol is a crosslinked porcine dermal collagen surgical mesh. It is an internal implant intended for use as a soft tissue patch to reinforce soft tissue where weakness exist and for the surgical repair of damaged or ruptured soft tissue membranes. Permacol is supplied in hydrated, ready to use sheets of various sizes. It comes in two thicknesses (1.0 mm and 1.5 mm) to address surgeon preference and the patient's clinical features.

**CMS HCPCS Preliminary Decision:**
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector.

**Summary of Primary Speaker Comments at the Public Meeting:**
The primary speaker disagreed with the workgroup's preliminary decision. According to the speaker, the inability to track Permacol through a specific code causes problems for physicians and hospitals that use the product in terms of cost and reimbursement tracking; clinical outcomes tracking; and supply chain tracking. The speaker stated that an HCPCS code does not exist to describe Permacol, and "Clinical choices which impact patient outcomes are influenced by the availability, or lack of availability of a code that accurately describes the product being used."

**HCPCS Public Meeting Agenda Item #16**
**April 28, 2009**

**Attachment: #09.033**

**Topic/Issue:**
Request to establish a code for reconstructive Tissue Matrix [LTM Surgical Mesh], trade name: Strattice®. Applicant's suggested language Q41XX "Tissue, Strattice, per square centimeter"

**Background/Discussion:**
According to the requester, Strattice® is a reconstructive tissue matrix (surgical mesh) that supports tissue regeneration. It is derived from porcine dermis and undergoes non-damaging proprietary processing that removes cells and significantly reduces the key component believed to play a major role in the xenogeneic rejection response. Strattice® is used by surgeons as a surgically implanted soft tissue patch to reinforce a patient's soft tissue where weakness exists, and for the surgical repair of damaged or ruptured soft tissue, such as in hernia repair, open abdominal repairs and in breast reconstruction, post mastectomy. Strattice® is supplied in 2 versions: pliable and firm, in sizes varying from 20 to 400 square cm. Once implanted, Strattice promotes rapid revascularization [cell repopulation and white cell migration] and provides for strong repair of the patients damaged tissue.

**CMS HCPCS Preliminary Decision:**
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector.

**Summary of Primary Speaker Comments at the Public Meeting:**
The speaker disagreed with the workgroup's preliminary decision, provided a brief overview of the technology centering on the medical necessity of the product, and reiterated the original request to establish a code. The speaker stated that there is a programmatic need to establish a code to track utilization and for accurate billing by facilities.

**HCPCS Public Meeting Agenda Item #17**
**April 28, 2009**

**Attachment: #09.047**

**Topic/Issue:**
Request to establish a code for Donated Human Tissue/Skin Allograft, trade name: AlloSkin. Applicant's suggested language: "Dermal and epidermal (substitute) tissue of human origin, with or without other bioengineered or processed elements, without metabolically active elements, per square centimeter"

**Background/Discussion:**
According to the requester, AlloSkin is an allograft made from donated human skin consisting of epidermal and dermal layers. It is processed and frozen at -40 degrees Centigrade or below in a manner that allows for both the preservation and stabilization of the graft. AlloSkin is indicated for use on all external wounds and is generally utilized on partial and full thickness wounds. It covers exposed bone, tendons, nerves and muscle, providing protection from infection and allowing time for the wound to heal. This product is supplied per square centimeter. AlloSkin is distinctly different from other tissue, such as Apligraf or Dermagraft which are engineered skin substitutes that possess metabolically active elements.

**CMS HCPCS Preliminary Decision:**
Use newly established Q4115 "SKIN SUBSTITUE, ALLOSKIN, PER SQUARE CENTIMETER" effective 7/1/09.

**Summary of Primary Speaker Comments at the Public Meeting:**
There was no primary speaker for this item.

**HCPCS Public Meeting Agenda Item #18**
**April 28, 2009**

**Attachment: #09.072**

**Topic/Issue:**
Request to establish a new "J" code for Fibrin Sealant VH S/D 4 (human), trade name: ARTISS [Fibrin Sealant (Human)]. Applicant's suggested language: Fibrin Sealant VH S/D 4 (human), per ml (ARTISS [Fibrin Sealant (Human)]).

**Background/Discussion:**
According to the requester, ARTISS is a two-component "slow-set" fibrin sealant consisting of human fibrinogen and low concentrated human thrombin (4IU) imitating the last step of the coagulation cascade. Mixing these 2 biologic components, together with calcium chloride, transforms soluble fibrinogen into a biocompatible fibrin matrix clot that adheres to connective tissue like a natural plasma clot. ARTISS is used as an alternative to staples or sutures to adhere autologous skin grafts to surgically prepared wound beds resulting from burns in adult and pediatric populations. ARTISS is for topical use only. It is applied to the wound bed as an aerosolized spray using the Easyspray and SpraySet, or an equivalent device cleared by the FDA for application of ARTISS. The skin graft should be applied to the wound bed immediately after ARTISS has been sprayed. ARTISS is available in two forms: as a pre-formulated lyophilized kit, or as a pre-filled syringe (frozen) that does not require further dilution or mixing. Either form is available in 2 mL, 4 mL and 10 mL (total volume) sizes. Vials and pre-filled syringes are for single-use only. The amount used varies based on the size of the graft: 2 mL for 100 sq. cm; 4 mL for 200 sq. cm; 10 mL for 500 sq. cm. Freeze-dried and pre-filled kits contain the following: ARTISS Kit (Freeze-Dried) 1. Sealer Protein Concentrate (Human), Vapor Heated, Solvent/Detergent Treated, Freeze-Dried, Sterile 2. Fibrinolysis Inhibitor Solution (Synthetic), Sterile 3. Thrombin (Human), Vapor Heated, Solvent/Detergent Treated, Freeze-Dried, Sterile 4. Calcium Chloride Solution, Sterile 5. DUPLOJECT Preparation and Application System (if indicated on the carton) ARTISS Pre-filled Syringe (Frozen) 1. (1) Sealer Protein Solution, Vapor Heated, Solvent/Detergent Treated, Sterile 2. (2) Thrombin Solution, Vapor Heated, Solvent/Detergent Treated Sterile 3. Sterile accessory devices (DUO Set: 1 plunger, 2 joining pieces and 4 application cannulas) are included with each pre-filled syringe According to the applicant, there are no codes that describe this product. ARTISS meets the "criteria for assignment to a unique HCPCS code "under rules governing single source drugs and biologicals defined in section 1847 of the Act."

**CMS HCPCS Preliminary Decision:**
A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector.

**Summary of Primary Speaker Comments at the Public Meeting:**

The primary speaker disagreed with the workgroup's preliminary decision. According to the speaker "ARTISS is a single source biological that is paid under section 1847A(b)(4) of the Act…" The speaker also claimed that there is a national program operating need to establish a code for ARTISS to simplify claim submission.

**HCPCS Public Meeting Agenda Item #19**
**April 28, 2009**

**Attachment: #09.022**

**Topic/Issue:**
Request to establish a "J" code for Antihemophilic Factor (Recombinant), Plasma/Albumin-Free. Trade name: XYNTHA. Requester's suggested language "Antihemophilic Factor (Recombinant), Plasma/Albumin-Free"

**Background/Discussion:**
According to the requester, XYNTHA Antihemophilic Factor (Recombinant), Plasma/Albumin-Free is indicated for the control and prevention of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia) and for surgical prophylaxis in patients with hemophilia A. XYNTHA is a completely albumin-free recombinant factor VIII product that uses a state-of-the-art purification process entirely free of human and animal materials. XYNTHA is the only recombinant factor VIII product purified using a patented man-made molecule known as synthetic ligand. XYNTHA is the only recombinant factor VIII product that uses a filtration step called nanofiltration. Antihemophilic Factor (Recombinant), Plasma/Albumin-Free, the active ingredient in XYNTHA, is a recombinant coagulation factor VIII produced by recombinant DNA technology for use in therapy of factor VIII deficiency. Factor VIII is the specific clotting factor deficient of patients with hemophilia A (classical hemophilia). Dosage and duration of treatment depend on the severity of the factor VIII deficiency, the location and extent of bleeding, and the patient's clinical condition. Doses administered should be titrated to the patient's clinical response. XYNTHA is supplied in kits that include single-use (Freeze-Dried) vials that contain nominally 250, 500, 1000, or 2000 IU per vial. Actual factor VIII activity in IU is stated on the label of each vial. In addition, each kit contains: one pre-filled diluent syringe containing 4 mL 0.9% Sodium chloride with plunger rod for assembly, one vial adapter, one sterile infusion set, two alcohol swabs, one bandage, one gauze, and one package insert. XYNTHA is administered by IV infusion after reconstitution with the supplied diluent. The required dosage is determined using this formula: Required units=body weight (kg) “x” desired factor VIII rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL). Frequency of intravenous injection is determined by the type of bleeding episode and the recommendation of the treating physician.

**CMS HCPCS Preliminary Decision:**
1) Newly established code Q2023 "INJECTION, FACTOR VIII (ANTIHEMOPHILIC FACTOR, RECOMBINANT) (XYNTHA), PER I.U. (effective 7/1/09) adequately describes the product that is the subject of your request.
2) Discontinue code Q2023 effective 12/31/09
3) Establish Jxxxx INJECTION, FACTOR VIII (ANTIHEMOPHILIC FACTOR, RECOMBINANT) (XYNTHA), PER I.U. (effective 1/1/2010)

**Summary of Primary Speaker Comments at the Public Meeting:**

There was no primary speaker for this item.

**HCPCS Public Meeting Agenda Item #20**
**April 28, 2009**

**Attachment: #09.027**

**Topic/Issue:**
Request to establish a code for C1 Inhibitor (Human) for Intravenous Use, Freeze-Dried Powder for Reconstitution, trade name: Cinryze. Applicant's suggested language JXXXX "C1 Inhibitor (Human) nano-filtered, 500 Units"

**Background/Discussion:**
According to the requester, Cinryze is the only FDA approved C1 inhibitor (C1 INH) indicated for routine prophylaxis against angioedema attacks in adolescent and adult patients with C1 INH deficiency, also known as hereditary angioedema (HAE). HAE is an unpredictable, life-threatening, and debilitating genetic disorder, characterized by low antigenic and functional C1 INH levels (Type I HAE), or by normal or elevated C1 INH concentrations with low C1 INH functional activity (Type II HAE). Cinryze increases antigenic and functional serum levels of C1 inhibitor, thereby replacing the deficient C1 INH activity. Routine prophylaxis dosing is 1,000 units intravenous every 3 or 4 days. Cinryze is supplied in 8 mL vials containing 500 units (lyophilized).

**CMS HCPCS Preliminary Decision:**
Establish Jxxxx INJECTION, C1 ESTERASE INHIBITOR (HUMAN), 10 UNITS

**Summary of Primary Speaker Comments at the Public Meeting:**
The primary speaker agreed with the workgroup's preliminary decision to establish a code, but requested that the word "nanofiltration" be added to the code descriptor to distinguish between nanofiltered and non-nanofiltered products.

**HCPCS Public Meeting Agenda Item #21**
**April 28, 2009**

**Attachment: #09.023**

**Topic/Issue:**
Request to establish a code for romiplostim, trade name: Nplate. Applicant's suggested language: JXXXX "Injection, romiplostim, 10 mcg"

**Background/Discussion:**
According to the requester, Nplate (romiplostim) is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteriods, immunoglobulins, or splenectomy. Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Nplate should not be used in an attempt to normalize platelet counts. Nplate is a novel engineered therapeutic fusion protein with attributes of both peptides and antibodies, but is distinct from each. Nplate works similarly to thrombopoietin (TPO), a natural protein in the body. Nplate stimulates the TPO receptor, which is necessary for growth and maturation of bone marrow cells that produce platelets. The initial dose of Nplate is 1 mcg/kg once weekly as a subcutaneous (SC) injection. The weekly dose may be adjusted by increments of 1 mcg/kg as necessary to reduce risk for bleeding. Maximum weekly dose of 10 mcg/kg is not to be exceeded. Nplate is provided in a dispensing pack containing a 5 mL vial and either 250 mcg or 500 mcg of deliverable romiplostim.

**CMS HCPCS Preliminary Decision:**
Establish Jxxxx INJECTION, ROMIPLOSTIM, 10 MICROGRAMS

**Summary of Primary Speaker Comments at the Public Meeting:**
The primary speaker agreed with CMS' preliminary decision to establish a code and agreed with the proposed language and dose descriptor. The speaker suggested that this decision be finalized. He stated that "this code will streamline and clarify coding for Immune thrombocytopenic purpura IPT."

**HCPCS Public Meeting Agenda Item #22**
**April 28, 2009**

**Attachment: #09.018**

**Topic/Issue:**
Request to establish a code for rilonacept, trade name: ARCALYST®.

**Background/Discussion:**
According to the requester, ARCALYST® (rilonacept), Injection (2mL,160mg) for Subcutaneous Use, an interleukin-1 blocker, is the first and only approved therapy indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. The incidence of CAPS in the U.S. is estimated to be 1 in 1 million or 300 to 500 patients. ARCALYST® is a targeted inhibitor of interleukin-1 (IL-1), the key driver of inflammation in CAPS. ARCALYST® is administered by subcutaneous injection. It is supplied in sterile, single-use, 20 mL vials containing 220 mg of rilonacept as a lyophilized powder for reconstitution. Adult patients 18 years of age and older initiate treatment with a loading dose of 320 mg delivered as two, 2-mL, subcutaneous injections of 160 mg on the same day at two different sites. Dosing continues with a once weekly 160 mg injection. ARCALYST® should not be administered more often, than twice weekly. Pediatric patients aged 12-17 years initiate treatment with a loading dose of 4.4 mg/kg, up to a maximum of 320 mg, delivered as one or two subcutaneous injections with a maximum single injection volume of 2 mL. ARCALYST® should be discontinued if a patient develops a serious infection.

**CMS HCPCS Preliminary Decision:**
Establish Jxxxx INJECTION, RILONACEPT, 1MG

**Summary of Primary Speaker Comments at the Public Meeting:**
There was no primary speaker for this item.

**HCPCS Public Meeting Agenda Item #23**
**April 28, 2009**

**Attachment: #09.073**

**Topic/Issue:**
Request to establish a new "J" code for Certolizumab Pegol, trade name: CIMZIA. Applicant's suggested language: Injection, Certolizumab Pegol, 200mg.

**Background/Discussion:**
According to the requestor, CIMZIA is a tumor necrosis factor (TNF) blocker indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. CIMZIA is administered via two separate subcutaneous injections. The recommended initial adult dose of CIMZIA for Crohn's disease is 400mg (given as two subcutaneous injections of 200 mg), and 400 mg again at weeks 2 and 4 respectfully. In patients who obtain a clinical response, the recommended maintenance regimen is 400 mg every four weeks. CIMZIA is supplied in packs containing two vials of 200 mg of lyophilized CIMZIA for reconstitution; two 2 mL vials containing 1 mL sterile water for injection; two 3 mL plastic syringes; four 20-gauge and two 23-gauge needles; and eight alcohol swabs.

**CMS HCPCS Preliminary Decision:**
Establish Jxxxx INJECTION, CERTOLIZUMAB PEGOL, 1MG

**Summary of Primary Speaker Comments at the Public Meeting:**
There was no primary speaker for this item.

**HCPCS Public Meeting Agenda Item #24**
**April 28, 2009**

**Attachment: #09.102**

**Topic/Issue:**
Request to revise the dose descriptor of existing code J7322 to facilitate accurate coding for Synvisc-ONE(TM). Current language: J7322 HYALURONAN OR DERIVATIVE, SYNVISC, FOR INTRA-ARTICULAR INJECTION, PER DOSE. Applicant's suggested language: "Hyaluronan or derivative, Synvisc or Synvisc One, for intra-articular injection, per 16 mg".

**Background/Discussion:**
According to the requester, Synvisc-ONE is an elastoviscous fluid containing hylan. It is indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to non-pharmacologic and simple analgesics. Synvisc-ONE will be administered as a single intra-articular injection of 48 mg of hylan G-F 20. The therapy will offer up to 26 weeks of pain relief. The product will be supplied in a single 10 ml vial containing 48 mg of Hylan G-F 20. Current HCPCS code J7322 does not adequately describe Synvisc-ONE because it is designated for Synvisc, a multiple intra-articular injection regimen of hylan delivered once per week for three weeks. Providers bill 1 unit of J7322 for each weekly 16 mg injection. Synvisc-ONE will be administered as a single intra-articular injection of 48 mg of Hylan G-F 20, supplied in a single syringe. According to the requester, the "Per dose" nomenclature of J7322, without a milligram annotation, is inappropriate for billing Synvisc-ONE. Providers can not bill for 3 units of J7322 to reflect Synvisc-ONE administration because this coding is not permitted under payer policies and guidelines and will cause confusion and inappropriate payment. Payer systems will not be able to process claims appropriately without a milligram component.

**CMS HCPCS Preliminary Decision:**
1) Discontinue code J7322
2) Establish Jxxxx HYALURONAN OR DERIVATIVE, SYNVISC OR SYNVISC-ONE, FOR INTRA-ARTICULAR INJECTION, 1 MG

**Summary of Primary Speaker Comments at the Public Meeting:**
The primary speaker thanked CMS for its preliminary decision and endorsed the proposal to combine Synvisc and Synvisc-One into a single, new code based on a “per 1 milligram” dose descriptor “for payment purposes.”

# 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

For 2005, Medicare provided a furnishing fee of $0.14 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.

For 2009, the furnishing fee is $0.164 per unit of clotting factor. For subsequent years, the furnishing fee for blood clotting factor will be increased by the percentage increase in the consumer price index for medical care for the 12-month period ending June of the previous year.

**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