Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Drugs, Biologicals, and Radiopharmaceuticals-Day 1
Wednesday, May 7, 2008

Introduction and Overview

Approximately 85 people attended. The agenda included 24 items.

John Warren of CMM presented an educational overview (attached) of Medicare payment for part B drugs, biologicals and radiopharmaceuticals. For additional information, please see the following web links regarding Part B 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

Cindy Hake 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 website 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 input provided at the Public Meetings regarding 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
Wednesday, May 7, 2008, 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 #08.73
Request to revise existing code J0585 which currently reads: "botulinum toxin type A, per unit", trade name: BOTOX®.

No Primary Speaker

AGENDA ITEM #2
Attachment #08.06
Request to establish 2 codes for methoxy polyethylene glycol-epoetin beta, trade name: Mircera®.

Primary Speaker: James Scott of Hoffmann-La Roche, Inc.

AGENDA ITEM #3
Attachment #08.131
Request to make four changes to clarify the nomenclature used to describe the products in existing codes J7340 – J7349.

No Primary Speaker

AGENDA ITEM #4
Attachment #08.87
Request to establish a code for GammaGraft®.

Primary Speaker: Martha Christian of Princeton Reimbursement Group

AGENDA ITEM #5
Attachment #08.29
Request to establish a code for dexrazoxane, trade name: Totect.

Primary Speaker: Lisa Schulmeister on behalf of TopoTarget

AGENDA ITEM #6
Attachment #08.07
Request to establish a code for anithemophilic factor FVIII/von Willebrand Factor Complex, trade name: Alphanate®.

Primary Speaker: Chris Healey of Grifols, Inc.

AGENDA ITEM #7
Attachment #08.25
Request to establish (2) codes for sodium chloride injection, USP 0.9%. Trade name: Sodium Chloride Injection, USP 0.9%.

Primary Speaker: Herbert Neuman, M.D.

AGEDNA ITEM #8
Attachment #08.91
Request to establish a code for tositumomab and iodine I-131 tositumomab, a component of the Bexxar® therapeutic regiment.

Attachment #08.92
Request to revise code A9544.

Primary Speaker: Roger Hunter of GlaxoSmithKline

AGENDA ITEM #9
Attachment #08.124
Request to establish a code for 18F-Sodium Fluoride injection.

No Primary Speaker

AGENDA ITEM #10
Attachment #08.61
Request to revise existing code A9502.

No Primary Speaker

AGENDA ITEM #11
Attachment #08.74
Request to establish a code for doripenem monohydrate for injection, trade name: Doribax™.

No Primary Speaker

AGENDA ITEM #12
Attachment #08.32
Request to establish two (2) codes for Topotecan capsules, trade name: HYCAMTIN®.

No Primary Speaker

AGEDNA ITEM #13
Attachment #08.33
Request to establish a code for temsirolimus injection kit for IV infusion only, trade name: TORISEL™.

No Primary Speaker

AGENDA ITEM #14
Attachment #08.38
Request to establish a code for triamcinolone acetonide injectable suspension 40mg/mL, trade name: TRIESENCE™ suspension.

Primary Speaker: Michael Kapin of Alcon Laboratories, Inc.

AGENDA ITEM #15
Attachment #08.55
Request to establish a code for Formoterol Fumarate solution in one 2 mL delivery vial, trade name: Perforomist™ Inhalation Solution.

Primary Speaker: Paul Campbell of EBG Advisors

AGENDA ITEM #16
Attachment #08.09
Request to establish a code for intravenous immune globulin, trade name: Flebogamma® 5% DIF.

No Primary Speaker

AGENDA ITEM #17
Attachment #08.16
Request to establish a code for human intravenous, immune globulin, trade name: Privigen®.

Primary Speaker: Stuart Langbein of Hogan & Hartson LLP

AGENDA ITEM #18
Attachment #08.28
Request to establish a code for Alpha – Proteinase Inhibitor (Human), trade name: Zemaira.

Primary Speaker: Stuart Langbein of Hogan & Hartson LLP

AGEDNA ITEM #19
Attachment #08.31
Request to establish a code for a lidocaine hydrochloride monohydrate powder intradermal injection system, trade name: Zingo™.

Primary Speaker: Diana Davidson of Anesiva, Inc.

AGEDNA ITEM #20
Attachment #08.72
Request to establish a "J" code for testosterone pellets, 75 mg, trade name: Testopel®. Testopel® currently maintains a temporary code (S0189) but not a unique J-code.

Primary Speaker: Bob Whitehead of Slate Pharmaceuticals, Inc.

AGEDNA ITEM #21
Attachment #08.82
Request to establish a code for etoposide phosphate, trade name: ETOPOPHOS®.

Primary Speaker: Collier Smyth, M.D.

AGEDNA ITEM #22
Attachment #08.84
Request to establish a code for levetiracetam injection, trade name: KEPPRA®.

No Primary Speaker

AGEDNA ITEM #23
Attachment #08.114
Request to establish a code for fosaprepitant dimeglumine for injection, trade name: Emend®.

Primary Speaker: Michael Trigg, M.D.

AGENDA ITEM #24
Attachment #08.136
Request to revise the dosage descriptor in existing codes J2788 and J2790 by changing the unit of measure from mcg to international units.

Primary Speaker: Ashok Chainani of Talecris Biotherapeutics

HCPCS Public Meeting Agenda #1
May 7, 2008

Attachment #08.73

Topic/Issue:
Request to revise existing code J0585 which currently reads: "botulinum toxin type A, per unit", trade name: BOTOX®. Applicant's suggested language: "onaclostox, per unit"

Background/Discussion:
According to the requester, BOTOX® is a physician-injected, orphan biologic, approved for the treatment of strabismus, blepharospasm, cervical dystonia, and severe primary axillary hyperhidrosis. The biologic Licensing Application (BLA) for BOTOX® described this product as "botulinum toxin type A" consistent with clinical literature references to botulinum toxins by serotype. Because there was no other botulinum toxin type A in development in the US at the time, no consideration was given to applying for a unique nonproprietary name or HCPCS descriptor for BOTOX®. No two botulinum toxin biologics are interchangeable. Units of one type A serotype biologic are not interchangeable with units of any other type A serotype – e.g., the mean BOTOX® dose in cervical dystonia is 236 [Allergan] units whereas the initial recommended dose of Dysport® (a different serotype A botulinum toxin) for cervical dystonia is 500 [Ipsen] units. With the anticipated introduction of other "botulinum toxin type A" biologics beginning in 2008, Allergan recognized the risk of confusion and in 2006 requested a unique nonproprietary USAN name for BOTOX®. USAN has finalized the adoption of the name "onaclostox" as a unique nonproprietary (generic) name for BOTOX®. According to the requester, the FDA has accepted the USAN name. Other serotype "A" botulinum toxins would be assigned different non-proprietary names. BOTOX® is supplied in a single-use vial, each vial contains 100 [Allergan] units of vacuum-dried Clostridium botulinum Type A neurotoxin complex derived from the Hall strain.

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 #2
May 7, 2008

Attachment #08.06

Topic/Issue:
Request to establish 2 codes for methoxy polyethylene glycol-epoetin beta, trade name: Mircera®. Applicant's suggested language: Jxxxx "Injection, methoxy polyethylene glycol-epoetin beta, 1 mcg (non-ESRD use)" and Jxxxx "Injection, methoxy polyethylene glycol-epoetin beta, 1 mcg (ESRD use)"

Background/Discussion:
According to the requester, Mircera is a novel Erythropoiesis-Stimulating Agent (ESA) intended for the treatment of anemia associated with chronic kidney disease including patients on dialysis and patients not on dialysis. Mircera is formulated as a sterile, preservative-free protein solution for intravenous (IV) or subcutaneous (SC) administration. It restores hemoglobin levels in chronic kidney disease patients by mimicking the body's natural red blood cell production. According to the requester, studies show that Mircera effectively corrected anemia with a once every two week regimen and provided stable and sustained hemoglobin levels when administered up to once monthly. Mircera is supplied in pre-filled syringes and single-use vials. With a prolonged half-life, Mircera should be administered less frequently than the other ESAs. The half life is similar, 139 hours (SC) and 134 hours (IV). It should be administered every two weeks or once monthly during maintenance treatment when converting from another ESA and every two weeks in correction, whereas, epoetin alfa is administered three times a week, and darbepoetin alfa is administered weekly or every two weeks. Mircera should be administered under the direction of a healthcare professional. According to the requester, Mircera is unique because currently there are no other products that share the same interaction at the receptor level, chemical structure, half-life or up to once monthly dosing schedule.

CMS HCPCS Preliminary Decision:
Provisional decision pending marketing in the U.S. to establish 2 "J" codes as follows:

Jxxx1 "INJECTION, METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA, (FOR ESRD ON DIALYSIS), 1 MICROGRAM"

Jxxx2 "INJECTION, METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA, (NON –ESRD USE), 1 MICROGRAM"

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker thanked CMS for it's preliminary decision to establish 2 codes for Mircera and requested that this decision be finalized.

HCPCS Public Meeting Agenda #3
May 7, 2008

Attachment #08.131

Topic/Issue:
Request to make four changes to clarify the nomenclature used to describe the products in existing codes J7340 – J7349. Specifically: (1) omit terminology that refers to "metabolically active elements"; (2) omit the term "with or without bioengineered or processed elements"; (3) adopt descriptors that are in synch with language in CPT coding; and (4) add product names in parentheses in the HCPCS code text, for clarity.

Background/Discussion:
According to the requester, current descriptors for codes J7340 – J7349 have confusing language in them, so it is difficult for health care providers and coders to select the appropriate J code. Therefore, four changes are recommended to clarify the nomenclature of these codes. The first suggested change pertains to one of the differentiating phrases in the descriptors that lack a commonly understood definition – whether the product is with or without "metabolically active elements". Because there is no clear guidance to discern whether a product does or does not contain metabolically active elements, it is recommended that this language be removed from the code descriptors. The second recommended change is that the language "with or without bioengineered or processed elements" be removed from the descriptors of all of these codes because this verbiage adds language to the descriptors without differentiating among the products. The third recommended change is to utilize the recent work of the American Medical Association (AMA) in its changes to Current Procedural Terminology (CPT) codes for procedures utilizing these products. Specifically, the AMA has identified the applicable procedure CPT codes for many of the products billed under J7340 – J7349 through the October 2006 CPT Assistant. HCPCS code descriptors should be in sync with the language used in the CPT codes to distinguish the products. Finally, it is recommended that all of these codes include the product name in parentheses as the agency has done for some of these codes for purposes of clarity for the coders.

Current code text:
J7340 "Dermal and epidermal, (substitute) tissue of human origin, with or without bioengineered or processed elements, with metabolically active elements, per square centimeter"
J7341 "Dermal (substitute) tissue of non-human origin, with or without other bioengineered or processed elements, with metabolically active elements, per square centimeter"
J7342 "Dermal (substitute) tissue of human origin, with or without other bioengineered or processed elements, with metabolically active elements, per square centimeter
J7343 "Dermal and epidermal, (substitute) tissue of non-human origin, with or without other bioengineered or processed elements, with metabolically active elements, per square centimeter"

J7344 "Dermal (substitute) tissue of human origin, with or without other bioengineered or processed elements, with metabolically active elements, per square centimeter"
J7346 "Dermal (substitute) tissue of human origin, injectable, with or without other bioengineered or processed elements, but without metabolically active elements, 1 cc
J7347 "Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, without metabolically active elements (Integra Matrix), per square centimeter"
J7348 "Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, without metabolically active elements (Tissuemend), per square centimeter"
J7349 "Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, without metabolically active elements (Primatrix), per square centimeter"

Applicant's suggested language revisions:
J7340 "Dermal and epidermal (substitute) tissue, of human origin, tissue cultured allogenic skin substitute (Apligraf/Orcel)"
J7341 "Dermal (substitute) tissue of nonhuman origin, acellular xenogenic implant (Oasis)"
J7342 "Dermal (substitute) tissue of human origin, tissue cultured allogenic dermal substitute (Dermagraft, DermagraftTC)"
J7343 "Dermal and epidermal (replacement) tissue, of nonhuman origin, acellular dermal replacement (Integra Dermal Regeneration Template/Integra Bilayer Matrix)"
J7344 "Dermal (substitute) tissue of human origin, acellular dermal allograft (GraftJacket)"
J7346 "Dermal (substitute) tissue of human origin, injectable, acellular dermal allograft (GraftJacket Express/Cymetra)"
J7347 "Dermal (substitute) tissue of nonhuman origin, acellular dermal replacement (Integra Matrix)"
J7348 "Dermal (substitute) tissue of nonhuman origin, (Tissuemend)"
J7349 "Dermal (substitute) tissue of nonhuman origin, acellular xenogenic implant (Primatrix)"

CMS HCPCS Preliminary Decision:
Revise existing code J7340 which currently reads: "DERMAL AND EPIDERMAL (SUBSTITUTE) TISSUE OF HUMAN ORIGIN, WITH OR WITHOUT BIOENGINEERED OR PROCESSED ELEMENTS, WITH METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER" to instead read: "DERMAL AND EPIDERMAL (SUBSTITUTE/REPLACEMENT) TISSUE OF HUMAN ORIGIN, WITH METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER"

Revise existing code J7341 which currently reads: "DERMAL (SUBSTITUTE) TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT BIOENGINEERED OR PROCESSED ELEMENTS, WITH METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER" to instead read: "DERMAL

(SUBSTITUTE/REPLACEMENT) TISSUE OF NON-HUMAN ORIGIN, WITH METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER"

Revise existing code J7342 which currently reads: "DERMAL (SUBSTITUTE) TISSUE OF HUMAN ORIGIN, WITH OR WITHOUT BIOENGINEERED OR PROCESSED ELEMENTS, WITH METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER" to instead read: "DERMAL (SUBSTITUTE/REPLACEMENT) TISSUE OF HUMAN ORIGIN, WITH METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER"

Revise existing code J7343 which currently reads: "DERMAL AND EPIDERMAL (SUBSTITUTE) TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER" to instead read: "DERMAL AND EPIDERMAL (SUBSTITUTE/REPLACEMENT) TISSUE OF NON-HUMAN ORIGIN, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER"

Revise existing code J7344 which currently reads: "DERMAL (SUBSTITUTE) TISSUE OF HUMAN ORIGIN, WITH OR WITHOUT BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER" and to instead read: "DERMAL (SUBSTITUTE/REPLACEMENT) TISSUE OF HUMAN ORIGIN, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER"

Revise existing code J7346 which currently reads: "DERMAL (SUBSTITUTE) TISSUE OF HUMAN ORIGIN, INJECTABLE, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, BUT WITHOUT METABOLICALLY ACTIVE ELEMENTS, 1CC" to instead read: "DERMAL TISSUE OF HUMAN ORIGIN, INJECTABLE, WITHOUT METABOLICALLY ACTIVE ELEMENTS, 1CC"

Revise existing code J7347 which currently reads: "DERMAL (SUBSTITUTE) TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS (INTEGRA MATRIX), PER SQUARE CENTIMETER" to instead read: "DERMAL SUBSTITUTE/REPLACEMENT) TISSUE OF NON-HUMAN ORIGIN, WITHOUT METABOLICALLY ACTIVE ELEMENTS (INTEGRA MATRIX), PER SQUARE CENTIMETER"

Revise existing code J7348 which currently reads: "DERMAL (SUBSTITUTE) TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS (TISSUEMEND), PER SQUARE CENTIMETER" to instead read: "DERMAL (SUBSTITUTE/REPLACEMENT) TISSUE OF NON-HUMAN ORIGIN, WITHOUT

METABOLICALLY ACTIVE ELEMENTS (TISSUEMEND), PER SQUARE CENTIMETER"

Revise existing code J7349 which currently reads: "DERMAL (SUBSTITUTE) TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS (PRIMATRIX), PER SQUARE CENTIMETER" to instead read: "DERMAL (SUBSTITUTE/REPLACEMENT) TISSUE OF NON-HUMAN ORIGIN, WITHOUT METABOLICALLY ACTIVE ELEMENTS (PRIMATRIX), PER SQUARE CENTIMETER"

Revised J7347 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 #4
May 7, 2008

Attachment #08.87

Topic/Issue:
Request to establish a code for GammaGraft®. Applicant's suggested language: "Human skin allograft tissue (dermal and epidermal), irradiated, with metabolically active elements, per square centimeter."

Background/Discussion:
According to the requester, GammaGraft® is an allograft; specifically human skin, consisting of the epidermal and dermal layers. It is processed and sterilized (utilizing gamma irradiation) in a manner that allows for both the preservation of the metabolically active elements within the graft and stabilization of the graft for storage at room temperature. GammaGraft® is a human tissue for transplantation for use on all external wounds. According to the applicant, GammaGraft® acts as a temporary substitute integument used to close the wound in place of the patient's own skin. GammaGraft® closes the wound, rendering it waterproof and closes the wound to infection. It is customarily used on partial and full thickness wounds and may be placed directly over bone and tendon. According to the requester, "existing HCPCS codes describe skin substitutes that mimic the properties of human skin and do not describe actual cadaver skin, thus requiring a code specific to an irradiated cadaver skin."

CMS HCPCS Preliminary Decision:
Establish Jxxxx "DERMAL AND EPIDERMAL (SUBSTITUTE/REPLACEMENT) TISSUE OF HUMAN ORIGIN, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER"

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with CMS' preliminary decision to establish a code, but disagreed with the proposed code verbiage characterizing GammaGraft® as without metabolically active elements "which does not link to an APC for payment". The speaker stated that "GammaGraft® does contain metabolically active elements". In addition, the speaker requested that the workgroup establish two unique codes to describe the two categories of human cadaver skin based on storage requirements, (fresh or frozen and room temperature stable).

HCPCS Public Meeting Agenda #5
May 7, 2008

Attachment #08.29

Topic/Issue:
Request to establish a code for dexrazoxane, trade name: Totect. Applicant's suggested language: "Dexrazoxane for injection, 500mg"

Background/Discussion:
According to the requester, Totect is indicated for the treatment of extravasation resulting from IV anthracycline chemotherapy. Totect reduces tissue damage from anthracycline extravasation, such as physical impairment, thus reducing the need for delaying chemotherapy. Totect powder is a sterile, pyrogen-free lyophilizate intended for intravenous administration. It is a bisdioxopiperazine that readily enters cells and is subsequently hydrolyzed to form a chelating agent analogous to EDTA. It is a catalytic inhibitor of DNA topoisomerase II and, in its ring-opened form ADR-925, a potent chelator of heavy metals. Totect is a time sensitive powder, and diluent for injection is supplied in a specialized per patient emergency treatment kit containing 10 vials of Totect powder and 10 vials of Totect solvent. Before infusion, each vial of Totect powder must be mixed with 50 ml Totect solvent. Then the mixed solution should be further diluted in 1000 ml 0.9% NaCl. The first infusion should be initiated as soon as possible within the first six hours after the accidental extravasation. It should then be given once daily for 3 consecutive days. The recommended dose is as follows: day one, 1000 mg/m2; day two 1000mg/m2; day three; 500mg/m2. Totect is administered IV over 1 to 2 hours. According to the requester, "Totect is different from other dexrazoxane products in terms of indications, dosing, administration, packaging, cost, orphan drug status, and pharmacoeconomic issues" and a unique HCPCS code will facilitate access to this product.

CMS HCPCS Preliminary Decision:
Existing code J1190 "INJECTION, DEXRAZOXANE HYDROCHLORIDE, PER 250 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 CMS' preliminary decision. The speaker stated that Totect is an orphan drug; that the FDA has determined that Totect has no therapeutic equivalents; and that dosing and administration for Totect is different than for Zinecard. The speaker claimed that Totect is a "single-source drug". The speaker also stated that use of code J1190 to identify Totect would be a "violation of patent".

HCPCS Public Meeting Agenda #6
May 7, 2008

Attachment #08.07

Topic/Issue:
Request to establish a code for anithemophilic factor FVIII/von Willebrand Factor Complex, trade name: Alphanate®.

Background/Discussion:
According to the requester, Alphanate is the only dual inactivated, affinity chromatography purified antihemophilic factor/von Willebrand Factor complex. Alphanate is a sterile, lyophilized concentrate intended for intravenous administration in the treatment of hemophilia A, acquired Factor VIII deficiency, and von Willebrand Disease. Alphanate is also approved for surgical or invasive procedures bleeding prophylaxis in patients with von Willebrand Disease, except Type 3 undergoing major surgery, in whom desmopressin (DDAVP) is either ineffective or contraindicated. The administration of Alphanate temporarily increases the plasma level of Factor VIII, thus minimizing the hazard of hemorrhage. Alphanate is prepared from pooled human plasma by cryoprecipitation of Factor VIII. Fractional solubilization, and further purification employing heparin-coupled, cross-linked agarose which has an affinity to the heparin binding domain of VWF/FVIII:C complex. This product is treated with a mixture of tri-n-butyl phosphate (TNBP) and polysorbate 80 to reduce the risks of transmission of viral infection. The product is also subjected to an 80 degree Celsius heat treatment step for 72 hours in order to provide an additional safeguard against potential non-lipid enveloped viral contaminants. Alphanate contains Albumin as a stabilizer, resulting in a final container concentrate with a specific activity of at least 5 FVIII:C IU/mg total protein. Alphanate is administered intravenously, and is supplied as a sterile, lyophilized powder in single dose vials. Dosages vary depending on condition and patient need.

CMS HCPCS Preliminary Decision:
Existing code Q4096 "INJECTION, VON WILLEBRAND FACTOR COMPLEX, HUMAN, RISTOCETIN COFACTOR (NOT OTHERWISE SPECIFIED), PER I.U. VWF:RCO" adequately describes the product that is the subject of your request.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker thanked CMS for code Q4096. However, the speaker requested that CMS establish a new code that accommodates both Anti-hemophilic Factor VIII and Von Willebrand Ristocetin Cofactor to assure access to appropriate therapy and minimize potential for billing errors. The speaker also stated that the pricing and reporting of the proposed code should be based on Factor VIII I.U. The speaker recommended discontinuation of code Q4096, but suggested that code J7190 be retained for other products.

HCPCS Public Meeting Agenda #7
May 7, 2008

Attachment #08.25

Topic/Issue:
Request to establish (2) codes for sodium chloride injection, USP 0.9%. Trade name: Sodium Chloride Injection, USP 0.9%. Requester suggested language: (a) Sodium Chloride Injection, USP 0.9%, in a prefilled syringe utilized during contrast enhanced imaging, delivered manually or by Mallincrodt power injector, 50 mL, (b) Sodium Chloride Injection, USP 0.9% in a prefilled syringe utilized during contrast enhanced imaging delivered by Mallincrodt power injector, 125 mL.

Background/Discussion:
According to the requester, this prefilled syringe of Sodium Chloride is indicated specifically for the use with contrast delivered manually or with Mallinckrodt power injectors in patients undergoing diagnostic imaging procedures. Its use in such procedures goes beyond the use of an ordinary saline flush. Sodium Chloride USP 0.9% used during contrast enhanced imaging procedures of the vasculature "pushes the contrast media into the venous system and adds extra volume to the tail of the bolus, which results in prolongation of the time to the peak aortic enhancement. Prolonging peak aortic enhancement allows for more consistent opacification through the entire scan volume." Thus, beyond flushing, the product directly enhances the performance of contrast and improves the quality of the diagnostic image. In addition, the use of saline in a prefilled syringe mitigates the opportunity for infection and medical error.

This product is available in 50 ml (NDC 0019-1188-75) and 125 ml (NDC 0019-1188-81) prefilled syringes. Both the 50 and the 125 ml are indicated for use with flushing compatible contrast agents through Mallinckrodt IV administration sets into indwelling intravascular access devices power injectors, however they are not compatible with the same power injectors. Only the 50 ml version can be delivered manually. According to the requester, this product is subject to Medicare Part B payment and ASP reporting, is approved under an NDA with no generic equivalents, it therefore meets the definition of a single-source drug in Section 1847A of the MMA, and therefore an appropriate HCPCS Level II code is warranted.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. CMS recommends that the applicant separately submit an inquiry to the American Medical Association (AMA) practice expense review subcommittee regarding inclusion of Sodium Chloride Injection, USP 0.9% when it is used in a procedure.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision and the HCPCS Workgroup's suggestion to submit a request to the AMA to consider the inclusion of this product into the CPT practice expense. The speaker stated that this product should have its own unique HCPCS code because it: 1) meets the definition of a single-source drug in Section 1847 of the Act; 2) enhances diagnostic imaging quality; 3) supports facility-based infection control efforts; and 4) supports facility-based efforts related to prevention of medical errors. According to the speaker, it is "not financially prudent" to include this particular product in the practice expense, because it is not used in every procedure.

HCPCS Public Meeting Agenda #8
May 7, 2008

Attachment #08.91

Topic/Issue:
Request to establish a code for tositumomab, a component of the Bexxar® therapeutic regimen. Applicant's suggested language: "Tositumomab, 450 mg."

Background/Discussion:
According to the requester, the Bexxar therapeutic regimen is indicated for the treatment of patients with CD20 antigen-expressing relapsed or refractory non-Hodgkin's lymphoma, including patients with Rituximab-refractory non-Hodgkin's lymphoma. Bexxar is a comprehensive therapeutic regimen administered in multiple steps over the course of a one to two-week period. Bexxar is a second line therapy used for those patients for whom first-line therapies have not achieved a good clinical outcome. The Food and Drug Administration (FDA) has approved this therapy as a single, one-time radioimmunotherapeutic intervention. No single component of the Bexxar therapeutic regimen is approved for use by itself. According to the requester, tositumomab is currently incorrectly classified as a supply and assigned a temporary G-code. However, all four components of the Bexxar therapeutic regimen are encompassed in the Medicare definition of drugs as a combination drug. The four regimen dose consists of one dosimetric dose of tositumomab, one dosimetric dose of Iodine I-131 tositumomab, one therapeutic dose of tositumomab, and one therapeutic dose of Iodine I-131 tositumomab. The dosing regimen includes a "cold" dose, "warm dose", and a "hot" dose. This application focuses on the dosimetric and therapeutic doses of tositumomab. At the beginning of the treatment regimen on Day 0, a 450 mg dosimetric cold dose is administered intravenously to a patient over 60 minutes, followed by a dosimetric warm does over 20 minutes. On day 7 or any subsequent day up to day 14, a 450 mg cold dose is administered, followed by an intravenous infusion of the hot dose. The hot dose amount is specific to each patient based on reactions to and data from the dosimetric warm dose given on Day 0. Bexxar is supplied as follows:

Dosimetric Packaging
- two single-use 225 mg vials and one single-use 35 mg vial of tositumomab
- a single use vial of Iodine I 131 Tositumomab containing not less than 20mL of Iodine I-131 Tositumomab

Therapeutic Packaging
- two single-use 225 mg vials and one single-use 35 mg vial of tositumomab
- one or two single use vial of Iodine I 131 Tositumomab containing not less than 20mL of Iodine I-131 Tositumomab

CMS HCPCS Preliminary Decision:

Existing code G3001 "ADMINISTRATION AND SUPPLY OF TOSITUMOMAB, 450 MG" adequately describes the product that is the subject of your request.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary coding decision and with Medicare payment for this product. The speaker stated that CMS treats the cold dose as a supply and underpays; and treats the warm dose as diagnostic and underpays. According to the speaker, the regimen includes Tositumomab and Iodine I-131 Tositumomab as antineoplastics. The speaker also stated that all four components of the Bexxar therapeutic regimen are encompassed in the Medicare definition of drugs as a combination drug (per section 50.1, Chapter 15 of the Medicare Benefit Policy Manual). The speaker reiterated the original request to establish a code that describes tositumomab as a drug and not as a supply, to reflect its role in the Bexxar therapeutic regimen.

HCPCS Public Meeting Agenda #8
May 7, 2008

Attachment #08.92

Topic/Issue:
Request to revise code A9544 "Iodine I-131 tositumomab, **diagnostic**, per study dose", to instead read: "Iodine I-131 tositumomab, **dosimetric**, per study dose."

Background/Discussion:
Tositumomab and Iodine I-131 tositumomab is a critical component of the Bexxar therapeutic regimen, indicated for the treatment of patients with CD20 antigen-expressing relapsed or refractory non-Hodgkin's lymphoma, including patient with Rituximab-refractory non-Hodgkin's lymphoma. The regimen is administered in multiple steps over the course of a one to two-week period. Bexxar is a second line therapy used for those patients for whom first-line therapies have not achieved a good clinical outcome. The Food and Drug Administration (FDA) has approved this therapy as a single, one-time radioimmuno-therapeutic intervention. No single component of the Bexxar therapeutic regimen is approved for use by itself. The entire regimen must be administered to a patient to achieve the desired clinical outcome. The purpose of administering the dosimetric dose is to determine the amount of radiolabeled monoclonal antibody required for the final therapeutic dose. This dosimetric dose, in fact, is not diagnostic, but rather represents the initiation of the radioimmuno-therapeutic regimen. According to the requester, the current descriptor of A9544 does not appropriately represent the agent or its purpose.

CMS HCPCS Preliminary Decision:
Existing codes A9544 "IODINE I-131 TOSITUMOMAB, DIAGNOSTIC, PER STUDY DOSE" and G3001 "ADMINISTRATION AND SUPPLY OF TOSITUMOMAB, 450 MG" adequately describe the product that is the subject of your request.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary decision. The speaker stated that the current descriptor does not describe the agent or its purpose. According to the requester, use of "diagnostic" is inaccurate because all components of Bexxar are intended to treat disease. In addition, identifying this product as diagnostic leaves hospital significantly underpaid because payment is bundled. The speaker reiterated the original request to revise code A9544 to replace the word "diagnostic" with "dosimetric".

HCPCS Public Meeting Agenda #9
May 7, 2008

Attachment #08.124

Topic/Issue:
Request to establish a code for 18F-Sodium Fluoride injection. Applicant's suggested language: "Sodium Fluoride F18, per dose up to 20 mCi"

Background/Discussion:
According to the requester, Sodium Fluoride F18 is a positron emitting radiopharmaceutical used for the evaluation of altered osteogenic activity. This radiopharmaceutical is injected into a patient who is then imaged on a Positron Emission Tomography (PET) scanner. Sodium Fluoride F18 is indicated for use in patients with altered osteogenic activity such as that which occurs with bone metastases in cancer patients. The radioactive fluoride, which is chemically identical to the naturally occurring fluoride in the body, is injected into the patient and allowed to circulate before scanning. As the Sodium Fluoride F18 circulates through the body it accumulates in sites of bone matrix formation or remodeling, such as a metastatic cancer to the bone or other disease processes such as Paget's disease or osteomyletis. Typical dosage of Sodium Fluoride F18 is 5 mCi – 15 mCi administered via an intravenous line. Usual parenteral dose for adult and adolescent skeletal imaging 10 mCi. Pediatric doses must be individualized by physician. Sodium Fluoride F18 is supplied in a unit dose syringe containing the labeled amount of no carrier added sodium 18F-Fluoride at the time of calibration. There are currently no existing HCPCS codes which describe Sodium Fluoride F18.

CMS HCPCS Preliminary Decision:
Establish Axxxx "SODIUM FLUORIDE F-18, DIAGNOSTIC, PER STUDY DOSE, UP TO 30 MILLICURIES"

Summary of Primary Speaker Comments at the Public Meeting:
There was no primary speaker for this item. Written comments were submitted by a representative of the applicant.

HCPCS Public Meeting Agenda #10
May 7, 2008

Attachment #08.61

Topic/Issue:
Request to revise existing code A9502 which currently reads: "Technetium Tc-99m tetrofosmin, diagnostic, per study dose, up to 40 millicuries" to instead read: "Technetium Tc-99m tetrofosmin, diagnostic, per study dose" by deleting "up to 40 millicuries" trade name: MYOVIEW™ kit.

Background/Discussion:
According to the requester, the verbiage of existing code A9502 is causing confusion among providers and payers, resulting in erroneous reporting of units administered. The "up to 40 millicuries" language was added to the code descriptor in 2006 with the intent of clarifying the typical dosage used in a myocardial perfusion study. Instead, it has been a source of confusion for providers and payers alike. Providers are not accurately reflecting the number of units administered. Moreover, they may not be receiving adequate reimbursement for the drug. According to the American Hospital Association's guidance in Coding Clinic Volume 6, Number 2, providers are advised to code and report the number of "study doses" that are administered based on the studies performed. In the January 1, 2007 cover letter for their 2008 HCPCS code applications and revision, the Society of Nuclear Medicine (SNM) requested that the HCPCS Panel remove the "up to" descriptors. The letter cited the abovementioned AHA guidance as well as SNM's own coding guidance on the subject. SNM also reiterated this request at the May 15, 2007 Public Meeting. Joining SNM in the request was the Council on Radionuclides and Radiopharmaceuticals (CORAR). GE Healthcare is a member of SNM's Nuclear Medicine APC Task Force as well as CORAR.

MYOVIEW™ (tetrofosmin) is myocardial perfusion agent indicated for scintigraphic imaging of the myocardium following separate administrations under exercise and/or resting conditions. It is also indicated to identify pharmacologic stress in patients with known or suspected CAD, and to access left ventricular function in evaluating patients for heart disease. The recommended dose is 5-33 mCi. For rest and stress imaging, 2 separate doses are used. One dose is given at rest. Another is given during the stress phase of the test. The first dose should be 5-12 mCi followed by the second dose of 15-33 mCi given approximately 1 to 4 hours later. MYOVIEW™ is supplied in a kit as a pack of 5 vials. Each vial contains a pre-dispensed, lyophilized mixture.

CMS HCPCS Preliminary Decision:
Revise existing code A9502 which currently reads: "TECHNETIUM TC-99M TETROFOSMIN, DIAGNOSTIC, PER STUDY DOSE, UP TO 40 MILLICURIES" to instead read: "TECHNETIUM TC-99M TETROFOSMIN, 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 #11
May 7, 2008

Attachment #08.74

Topic/Issue:
Request to establish a code for doripenem monohydrate for injection, trade name: Doribax™. Applicant's suggested language: "doripenem monohydrate for injection, 250mg"

Background/Discussion:
According to the requester, Doribax™ (doripenem for injection) is a penem antibacterial used to treat serious infections. Doribax is indicated as a single agent for the treatment of complicated intra-abdominal infections caused by Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Bacteroides caccae, Bacteroides fragilis, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Streptococcus intermedius, Streptococcus constellatus and Peptostreptococcus micros. Doribax is also indicated for complicated urinary tract infections, including pyelonephritis caused by Escherichia coli, including cases with concurrent bacteremia, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, and Acinetobacter baumannii. The recommended dosage is 500mg administered as an intravenous infusion over one hour every eight hours for up to fourteen days. Doribax is packaged in a single use vial containing 500 mg (on an anhydrous basis) of sterile doripenem powder. Current codes do not adequately describe Doribax. The benefits of a new, unique HCPCS code for this product will be two-fold: most importantly, it will facilitate patient access to this product, while it will also allow payer systems to capture important product-specific data. According to the requester, Doribax is not described by existing codes and a code is needed to facilitate patient access and to ease the administrative burden associated with miscellaneous coding.

CMS HCPCS Preliminary Decision:
Establish Jxxxx "INJECTION, DORIPENEM, 10 MG"

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

HCPCS Public Meeting Agenda #12
May 7, 2008

Attachment #08.32

Topic/Issue:
Request to establish two (2) codes for Topotecan capsules, trade name: HYCAMTIN®. Applicant's suggested language: (1) Topotecan, oral, 0.25 mg and (2) Topotecan, oral, 1 mg

Background/Discussion:
According to the requester, HYCAMTIN (topotecan) Capsules are indicated for the treatment of relapsed small cell lung cancer in patients with a prior complete or partial response to first-line chemotherapy and who are at least 45 days from the end of that therapy. HYCAMTIN belongs to a class of drugs known as topoisomerase I (topo-I) inhibitors. Topo-I is a naturally produced protein essential for cell division in both normal and cancer cells. Interaction between topo-I and HYCAMTIN (topotecan) Capsules results in permanent damage to the cell's genetic material and the death of dividing cells. The recommended dose of HYCAMTIN is 2.3 mg/m2/ rounded to the nearest 0.25 mg once daily for 5 consecutive days, repeated every 21 days. HYCAMTIN is orally administered and is supplied in two dosage formulations: 0.25 mg and 1 mg. HYCAMTIN (topotecan) Capsules share the same active ingredient as HYCAMTIN (topotecan hydrochloride) for Injection; however, HYCAMTIN (topotecan) Capsules provide for oral administration and a new dosing regimen. HYCAMTIN (topotecan hydrochloride) for Injection is currently covered under Part B. Given that the capsules and intravenous formulations share the same active ingredient and the capsule formulation is indicated for the treatment of relapsed small cell lung cancer, which is one of the indications for the intravenous formulation of topotecan, it is being considered for Part B coverage. The existing code for the intravenous formulation of topotecan (J9350 for topotecan, 4 mg) is inadequate to describe the 0.25 mg and 1 mg oral formulations of HYCAMTIN (topotecan) Capsules.

CMS HCPCS Preliminary Decision:
1) Establish Jxxxx "TOPOTECAN, ORAL, 0.25 MG"
2) Revise existing code J9350 which currently reads: "TOPOTECAN, 4MG" to instead read: "INJECTION, TOPOTECAN, 4MG". The proposed new code would adequately describe oral Topotecan. Doses can be billed in multiples on the claim form to report the amount administered.

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

HCPCS Public Meeting Agenda #13
May 7, 2008

Attachment #08.33

Topic/Issue:
Request to establish a code for temsirolimus injection kit for IV infusion only, trade name: TORISEL™. Applicant's suggested language: "Injection, temsirolimus, 25 mg"

Background/Discussion:
According to the requester, TORISEL is the first mammalian target of rapamycin inhibitor approved for a cancer indication. TORISEL has proven to prolong the median overall survival of patients with renal cell carcinoma of the poor-prognostic risk category. TORISEL in indicated for the treatment of advanced renal cell carcinoma. The recommended dose of TORISEL is 25mg IV, infused over 30-60 minutes once per week until disease progression or unacceptable toxicity. TORISEL is supplied as a kit containing one vial of TORISEL 25mg/mL (with an overfill of .02mL) and one vial of diluent, with a deliverable volume of 1.8mL. There are no existing HCPCS codes that identify TORISEL.

CMS HCPCS Preliminary Decision:
Establish Jxxxx "INJECTION, TEMSIROLIMUS, 1 MG"

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

HCPCS Public Meeting Agenda #14
May 7, 2008

Attachment #08.38

Topic/Issue:
Request to establish a code for triamcinolone acetonide injectable suspension 40mg/mL, trade name: TRIESENCE™ suspension. Applicant's suggested language: "Injection, ophthalmic use triamcinolone acetonide injectable suspension, preservative-free, 40 mg/mL"

Background/Discussion:
According to the requester, TRIESENCE™ suspension is a synthetic glucocorticoid corticosteroid with anti-inflammatory action. For treatment of ophthalmic conditions, the initial recommended dose of TRIESENCE™ suspension is 4 mg (100 µl of 40 mg/mL suspension) administered intravitreally with subsequent dosage as needed over the course of treatment. For visualization during vitrectomy, the initial recommended dose of TRIESENCE™ suspension is 1 to 4 mg (25 to 100 µl of 40 mg/mL suspension) administered intravitreally. TRIESENCE™ suspension is supplied in a 1 mL of 40 mg/mL triamcinolone acetonide suspension. While there are other injectable triamcinolone products on the market, TRIESENCE™ suspension has four clinically-relevant unique attributes: (1) it is the only FDA-approved injectable triamcinolone suspension for ophthalmologic use; (2) it's a unique preservative-free formulation and, therefore, is not associated with a risk of retinal toxicity; (3) it is terminally sterile and, therefore, has a lower probability of a non-sterile unit occurring; and (4) it has a tightly controlled particle distribution. Existing codes J3301 "INJECTION, TRIAMCINOLONE ACETONIDE, PER 10MG", J3302 "INJECTION, TRIAMCINOLONE DIACETATE, PER 5MG" and J3303 "INJECTION, TRIAMCINOLONE HEXACETONIDE, PER 5MG" does not adequately describe TRIESENCE™ suspension as they describe injectable triamcinolone products with different attributes. According to the requester, a unique code is needed in order to facilitate payment and access to a single-source drug.

CMS HCPCS Preliminary Decision:
1) Revise existing code J3301 which currently reads: INJECTION, TRIAMCINOLONE ACETONIDE, PER 10 MG to instead read J3301 INJECTION, TRIAMCINOLONE ACETONIDE, NOT OTHERWISE SPECIFIED, 10 MG eff. 1/1/09
2) Establish Jxxxx INJECTION, TRIAMCINOLONE ACETONIDE, PRESERVATIVE FREE, 1 MG

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with CMS' preliminary decision and stated that "the proposed new code is needed to uniquely identify Triesence suspension."

HCPCS Public Meeting Agenda #15
May 7, 2008

Attachment #08.55

Topic/Issue:
Request to establish a code for formoterol fumarate solution in one 2 mL delivery vial, trade name: Perforomist™ Inhalation Solution.

Background/Discussion:
According to the requester, Perforomist™ Inhalation Solution is a drug administered via a nebulizer. Perforomist will be the only FDA- approved and patented non-compounded formoterol fumarate product used in the treatment of bronchoconstriction in patients with Chronic Obstructive Pulmonary Disease (COPD). Administration of Perforomist via a nebulizer provides a significant bronchodilatory effect while avoiding patient technique errors often associated with dry powder inhalers. Existing code J7640 "FORMOTEROL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, 12 MICROGRAMS" describes a compounded product and because Perforomist is not a compounded product, this code is inappropriate for use in billing for Perforomist. It is well documented that a segment of the COPD patient population is unable to reliably administer their medications via MDI and/or DPI preparations and nebulization provides the only means to effectively and accurately provide treatment for these patients. Perforomist™ Inhalation Solution is for long-term, twice daily administration in the maintenance treatment, (as opposed to as-needed/rescue treatment) of bronchoconstriction in patients with COPD including chronic bronchitis and emphysema. Perforomist is supplied as a pre-mixed, pre-measured 2ml sterile solution for nebulization in a 2.5 ml unit dose vial containing 20 mcg of formoterol fumarate.

CMS HCPCS Preliminary Decision:
Existing code Q4099 "FORMOTERAL FUMARATE, INHALATION SOLUTION, FDA APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 20 MICROGRAMS" adequately describes the product that is the subject of your request.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with CMS' decision to establish a code, and agrees with the code descriptor. The speaker requested that Q4099 be converted to a permanent "J" code using the same language.

HCPCS Public Meeting Agenda #16
May 7, 2008

Attachment #08.09

Topic/Issue:
Request to establish a code for intravenous immune globulin, trade name: Flebogamma® 5% DIF.

Background/Discussion:
According to the requester, Flebogamma 5% DIF is a high purity, pasteurized, liquid product formulated with a sorbitol stabilizer, ready for administration. It is indicated for replacement therapy in primary (inherited) humoral immunodeficiency disorders, such as common variable immunodeficiency, x-linked agammaglobulinemia, severe combined immunodeficiency and Wiskott – Aldrich syndrome. Flebogamma DIF is especially useful when rapid replacement of IgG or the attainment of high serum levels of IgG is desired. Usual dosage for replacement therapy in primary humoral immunodeficiency diseases is 300 to 600 mg/kg body weight administered every 3 to 4 weeks, intravenously. Doses may be adjusted over time to achieve the desired trough IgG levels and clinical response. Flebogamma is supplied in single dose vials containing 0.5, 2.5, 5, 10, or 20 gram vials of IgG as a liquid solution.

CMS HCPCS Preliminary Decision:
Revise existing code J1572 which currently reads: "INJECTION, IMMUNE GLOBULIN, (FLEBOGAMMA), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG" to instead read: "INJECTION, IMMUNE GLOBULIN, (FLEBOGAMMA/FLEBOGAMMA DIF), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG". The proposed revision adequately describes Flebogamma DIF.

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

HCPCS Public Meeting Agenda #17
May 7, 2008

Attachment #08.16

Topic/Issue:
Request to establish a code for human intravenous, immune globulin, trade name: Privigen®.

Background/Discussion:
According to the requester, Privigen is immune globulin indicated for the treatment of chronic immune thrombocytopenic purpura (ITP) to rapidly raise platelet counts to prevent bleeding. It is used by patients with Primary immunodeficiency and ITP. Privigen contains a broad spectrum of antibody specificities consisting of at least 98% IgG. The mechanism of action of immunoglobulin is not fully understood. One possible mechanism may be the inhibition of the elimination of autoantibody-reactive platelets from the blood circulation by IgG-induced Fc-receptor blockade of phagocytes. Another proposed mechanism is the down-regulation of platelet autoantibody-producing B cells byanti-idiotypic antibodies in IGIV. In Primary Immunodeficiency, Privigen dosing ranges from, 200 to 800 mg/kg/body weight (bw), administered intravenously every 3 to 4 weeks, which temporarily restores IgG levels to normal range. Usual dosage is 1 g/kg bw administered intravenously for 2 consecutive days, resulting in a total dosage of 2 g/kg bw. Privigen should be given by a separate infusion line. Privigen is supplied in single use vials: 5 grams in 50 ml solution; 10 grams in 100 ml solution; and 20 grams in 200 ml solution.

CMS HCPCS Preliminary Decision:
Existing code Q4097 "INJECTION, IMMUNE GLOBULIN (PRIVIGEN), INTRAVENOUS, NON-LYOPHILIZED (E.G., LIQUID), 500 MG" adequately describes the product that is the subject of your request.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker thanked CMS for code Q4097 and agreed with the text and dose descriptor. The speaker requested that Q4097 be converted to a permanent "J" code.

HCPCS Public Meeting Agenda #18
May 7, 2008

Attachment #08.28

Topic/Issue:
Request to establish a code for Alpha – Proteinase Inhibitor (Human), trade name: Zemaira. Applicant's suggested language: "Injection, alpha-1 proteinase inhibitor – human (Zemaira), 10 mg"

Background/Discussion:
According to the requester, Zemaira is a treatment for patients suffering from alpha-1 antitrypsin deficiency. It is a highly purified plasma derived alpha1 proteinase inhibitor (A1-PI) indicated for chronic augmentation and maintenance therapy in individuals with alpha-1 antitrypsin deficiency and clinical evidence of emphysema. In healthy individuals, A1-PI binds to neutrophil elastase to prevent inappropriate proteolysis in lung tissue by unopposed neutrophil elastase. Individuals with severe A1-PI deficiency are unable to maintain an appropriate antiprotease defense, subjecting them to more rapid alveolar wall proteolysis, which leads to chronic lung disease. Weekly intravenous infusions of Zemaira augmentation therapy at a dose of 60mg/kg raises the serum A1-PI levels above the historical protective threshold of 11μM (80 mg/dl) and increases A1-PI levels in the epithelial lining fluid of the lower lung. The recommended dosage of Zemaira at 60 mg/kg body weight will take approximately 15 minutes to infuse. When reconstituted as directed, Zemaira may be administered at a rate of approximately 0.08 mL/kg/min as determined by the response and comfort of the patient. Individuals may infuse themselves, or be infused by a health care professional in the home, or an outpatient infusion center. Zemaira is supplied in a single use vial containing the amount of functionally active A1-PI in milligrams, stated on the label. This sterile, white lyophilized powder should be administered intravenously. Each product package contains one single use vial of Zemaira, one 20 mL vial of sterile water for injection, USP (diluent), and one vented transfer device. When reconstituted as directed on the approved labeling a 1 gm vial contains approximately 1000 mg of functionally active A1PI (minum of 900 mg). According to the requester, Zemaira was not included in existing code J0256 (INJECTION, ALPHA 1 PROTEINASE INHIBITOR, HUMAN, 10 MG) as of October 1, 2003, and therefore should be considered a single source drug and a unique, product-specific code is needed in order to correctly implement the "ASP Statute".

CMS HCPCS Preliminary Decision:
Existing code J0256 "INJECTION, ALPHA 1 - PROTEINASE INHIBITOR - HUMAN, 10 MG" adequately describes the product that is the subject of your request.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed that, as a matter of coding principles alone, J0256 adequately describes Zemaira, and that the descriptor language and the base dose for J0256 would be

appropriate for Zemaira. Nonetheless, a unique HCPCS code for Zemaira is necessitated by section 1847A of the SSA on the basis that "Zemaira was not within the same billing and payment code (i.e., HCPCS) code as any other products as of October 1, 2003."

HCPCS Public Meeting Agenda #19
May 7, 2008

Attachment #08.31

Topic/Issue:
Request to establish a code for a lidocaine hydrochloride monohydrate powder intradermal injection system, trade name: Zingo™. Applicant's suggested language: "Injection, lidocaine hydrochloride monohydrate powder intradermal system, 0.5mg"

Background/Discussion:
According to the requester, Zingo™ is a local anesthetic delivered through a needle-free intradermal injection system for use on intact skin to provide topical local analgesia prior to venipuncture or peripheral intravenous (IV) cannulation in children 3-18 years of age. Local analgesia occurs within 1-3 minutes and lasts approximately 10 minutes, so the health professional can administer the local anesthetic and perform the procedure in one encounter. Zingo™ is packaged as a ready-to-use, sterile, single use, needle-free, powder intradermal injection system containing 0.5mg lidocaine hydrochloride monohydrate. The injection system consists of a prefilled drug reservoir cassette, a small pressurized helium gas cylinder, and a safety interlock that prevents inadvertent administration. To administer, the clinician positions Zingo™ against the skin, pushes down to release the safety interlock, and presses the start button to actuate the product. Zingo™ is not indicated for patient self-administration. Zingo™ is a new injectable drug for which a specific HCPCS code does not currently exist. The applicant believes that Zingo would be considered a "single source drug or biological" under the Medicare Statute, section 1847A ©(6)(D) of the Social Security Act.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a code to identify this product. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For private insurers, contact the individual private insurance contractor. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For Medicare, supplies used for venous injection or infusion are part of the Practice Expense component of the physician payment. This is based on the reference in the CPT Manual under "Vascular Injection Procedures": "Listed services for injection procedures include necessary local anesthesia."

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary decision. According to the requester, local anesthetics are not included in the physician payment for IV administration codes. The speaker discussed the medical benefits of topical local anesthetic and the convenience related to rapid onset. The speaker stated that the existence of code J2001 for IV Lidocaine indicates that a code should exist for topical application. The speaker stated that a separate HCPCS code is needed to identify Zingo,

and to ensure patient access and provider reimbursement. The speaker also stated that a new code should be issued consistent with the agency's policy for implementing section 1847A of the Act.

HCPCS Public Meeting Agenda #20
May 7, 2008

Attachment #08.72

Topic/Issue:
Request to establish a "J" code for testosterone pellets, 75 mg, trade name: Testopel®. Testopel® currently maintains a temporary code (S0189) but not a unique J-code.

Background/Discussion:
According to the requester, Testopel® is the only FDA-approved testosterone pellet available in the United States. Testopel® is indicated for the treatment of primary hypogonadism; hypogonadotrophic hypogonadism; and to stimulate puberty in selected males with delayed puberty. Testopel® 75mg testosterone pellets are implanted subcutaneously. The pellets slowly release the hormone for a long acting androgenic effect, maintaining normal serum levels of testosterone for months. The dosage guideline for replacement therapy in androgen-deficient males is 150mg to 450mg subcutaneously every 3 to 6 months. Testopel is supplied as Testosterone pellets of 75mg, one pellet per vial in boxes of 10 and 100. According to the requester, there is a CPT code (11980) for the procedure to implant hormone pellets. And there is a HCPCS "S" code (S0189), however "there is no current J code assigned by CMS for Medicare reimbursement."

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to establish a J code to identify this product. Existing S0189 "TESTOSTERONE PELLET, 75 MG" is available for assignment by all insurers as they deem appropriate, in accordance with their policies and programs. For coding guidance, contact the insurer in whose jurisdiction a claim would be filed.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary decision, discussed medical necessity for this product, and requested that CMS reconsider the original recommendation to establish a code. According to the speaker, "private insurers are considering instituting coverage policies."

HCPCS Public Meeting Agenda #21
May 7, 2008

Attachment #08.82

Topic/Issue:
Request to establish a code for etoposide phosphate, trade name: ETOPOPHOS®. Applicant's suggested language: "Etoposide phosphate 100 mg for injection"

Background/Discussion:
According to the requester, ETOPOPHOS® for injection is an antineoplastic agent indicated in the management of Refractory Testicular Tumors and Small Cell Lung Cancer. ETOPOPHOS® is unique from etoposide. It is a phosphate ester of etoposide and is readily water soluble while etoposide has low water soluability and, therefore, is solubilized with citric acid, benzyl alcohol, modified polysorbate 80, and polyethylene glycol. ETOPOPHOS® for injection is supplied as single-dose vial containing etoposide phosphate equivalent to 100 mg etoposide. The usual dose of ETOPOPHOS® for injection in testicular cancer ranges from 50 to 100 mg/m2/day on days 1-5, to 100mg/m2/day on days 1,3 and 5. The usual dose in small cell lung cancer ranges from 35mg/m2/day for 4 days to 50mg/m2/day for 5 days. There are recommended dosing adjustments for patients with renal impairment. Chemotherapy courses are repeated at 3 to 4 week intervals after adequate recovery from toxicity. According to the requester, existing HCPCS codes J9181 and J9182 (Etoposide 10mg inj. And 100mg inj.) do not adequately describe ETOPOPHOS. Because its formulation avoids use of various excipients, ETOPOPHOS reduces administration related toxicities and potentially reduces overall infusion time and volume otherwise associated with Etoposide.

CMS HCPCS Preliminary Decision:
1) Discontinue J9182 "ETOPOSIDE, 100 MG" eff. 12/31/08
2) Revise existing code J9181 which currently reads: "ETOPOSIDE, 10 MG" to read: "INJECTION, ETOPOSIDE, 10 MG"
Code J9181 adequately describes ETOPOPHOS. Units can be billed in multiples to accurately report the amount administered.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary decision. The speaker stated that the difference in safety profiles (between etoposide and etoposide phosphate) related to administration and solution excipients create meaningful therapeutic differentiation; a key difference being water solubility and the fluid volume required to administer very high doses of etoposide. The speaker stated that the magnitude of differences between the products cannot be captured by a modification of existing codes. The speaker reiterated the original request to establish a unique code to facilitate patient access.

HCPCS Public Meeting Agenda #22
May 7, 2008

Attachment #08.84

Topic/Issue:
Request to establish a code for levetiracetam injection, trade name: KEPPRA®. Applicant's suggested language: "Injection, levetiracetam for intravenous infusion, 500mg"

Background/Discussion:
According to the requester, KEPPRA® injection is an antiepileptic drug used to treat partial onset seizures and myoclonic seizures in adults with juvenile myoclonic epilepsy (JME) as an adjunct therapy in adults (>16 years of age) when oral administration of KEPPRA is temporarily not feasible. KEPPRA injection is supplied in a single-use vial. One vial of KEPPRA injection contains 500mg levetiracetam (500mg/5mL). KEPPRA injection (500mg/5mL) should be diluted in 100 mL of a compatible diluent and administered intravenously as a 15-minute infusion. Recommended dosing for partial onset seizures and JME is 500mg twice daily, increased as needed and tolerated in increments of 1000mg/day every 2 weeks to a maximum daily dose of 3000 mg. The applicant requests "unique HCPCS J-code to facilitate…. claims processing and tracking, consistent with the CMS instructions to encourage hospitals to bill specific drugs and drug charges whether or not the payment for the drug is expected to be package into an APC."

CMS HCPCS Preliminary Decision:
Establish Jxxxx "INJECTION, LEVETIRACETAM, 10 MG"

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

HCPCS Public Meeting Agenda #23
May 7, 2008

Attachment #08.114

Topic/Issue:
Request to establish a code for fosaprepitant dimeglumine for injection, trade name: Emend®. Applicant's suggested language: "Injection, fosaprepitant dimeglumine, per 115mg"

Background/Discussion:
According to the requester, Emend® will be indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin, and prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. Emend® for injection is administered 30 minutes prior to chemotherapy as an infusion administered over 15 minutes. According to the applicant, if approved, the 3-day chemotherapy-induced nausea and vomiting (CINV) regimen will include Emend® for injection (115 mg) or Emend® (aprepitant) oral capsule (125mg) on Day 1; Emend® (aprepitant) oral capsule (80 mg) on Days 2 and 3; in combination with a corticosteroid and a 5-HT antagonist. Emend for injection will be supplied in 115mg single dose per 10ml vials. Existing code J8501 (Aprepitant, oral, 5mg) is available for Emend oral capsules but does not describe injectable Emend.

CMS HCPCS Preliminary Decision:
Establish Jxxxx "INJECTION, FOSAPREPITANT, 1MG"

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker agreed with CMS' 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 "115MG". According to the speaker, this change will minimize potential market confusion between the 125MG oral and 115MG intravenous products. The speaker stated that the only indication is for a full, 115 MG dose, and there are no pediatric indications at this time.

HCPCS Public Meeting Agenda #24
May 7, 2008

Attachment #08.136

Topic/Issue:
Request to revise the dosage descriptor in existing codes J2788 and J2790 by changing the unit of measure from mcg to international units for the two vial sizes: 250 IUs = 50mcg and 1500 IUs = 300mcg. Trade name: Hyper-RHO S/D.

Background/Discussion:
According to the requester, existing codes J2788 "INJECTION, RHO D IMMUNE GLOBULIN, HUMAN, MINIDOSE, 50 MCG" and J2790 "INJECTION, RHO D IMMUNE GLOBULIN, HUMAN, FULL DOSE, 300 MCG" identify Hyper-RHO (S/D) 50 mcg and 300 mcg unit sizes. The requester proposes a revision to the code descriptors from microgram to international units. Existing codes are adequate, however, the FDA's CBER requested that a change be made to the units on the vials to reflect international units. Doses have been modified to reflect international units per CBER guidance. It is therefore requested that 250 IUs be added to the listing for the Mini Dose and 1500 IUs be added in addition to the 300 mcg in the HCPCS listings. Hyper-RHO S/D Minidose is used to prevent the formation of anti-Rho(D) antibody in Rho(D) negative women who are exposed to the Rho(D) antigen at the time of spontaneous or induced abortion. After the 12^{th} week of gestation, a standard dose of Hyper-RHO S/D full dose is indicated. Hyper-RHO should be administered within 3 hours or as soon as possible following spontaneous or induced abortion.

CMS HCPCS Preliminary Decision:
No insurer (i.e., Medicare, Medicaid, Private Insurance Sector) identified a national program operating need to revise the dosage descriptors of these codes. Existing codes J2788 "INJECTION, RHO D IMMUNE GLOBULIN, HUMAN, MINIDOSE, 50 MCG" and J2790 "INJECTION, RHO D IMMUNE GLOBULIN, HUMAN, FULL DOSE, 300 MCG" adequately describe the products that are the subject of your request.

Summary of Primary Speaker Comments at the Public Meeting:
The primary speaker disagreed with CMS' preliminary decision. The speaker stated that the standard unit for RHO products is I.U. and requested that the international units be added to the current code descriptor. According to the speaker, from a coding perspective this is a compliance issue because the labeling includes international units only, not micrograms. The speaker offered a suggestion to add "I.U." units to the existing dose descriptor, rather than replace "mcg" with "I.U.". This change will enable compliance without changing packaging.

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 2008, the furnishing fee is $0.158 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