Centers for Medicare and Medicaid Services

HCPCS Public Meeting Agenda for May 11, 2006, 9:00 am – 5:00 pm DRUGS/BIOLOGICALS/ RADIOPHARMACEUTICALS/RADIOLOGIC IMAGING AGENTS (DAY 1)

Please note that this agenda contains preliminary decisions that may not necessarily reflect what the final decisions will be. Preliminary decisions provide a basis for comment at public meetings. All coding changes, when finalized will be published by mid November on the CMS HCPCS website at www.cms.hhs.gov/medhcpcsgeninfo, and will be effective January 1, 2007 unless otherwise noted in the HCPCS Annual Update or on a Quarterly Update.

The packet 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.

This meeting will begin at 9 a.m. and is scheduled to end at 5 p.m., E.S.T. However, because it is impossible to anticipate whether all presentations will fill their allotted time period (e.g. 15 minutes for Primary Speakers; or 5 minutes for "5-Minute Speakers"), we cannot commit specific items to specific time frames, and we can only estimate the amount of meeting time that will be needed. The meeting may end earlier than 5:00 p.m. Meeting participants should arrive early and plan on the meeting commencing promptly at 9:00 a.m., and speakers are asked to please arrive prepared and wait until it is their turn to speak.

Centers for Medicare & Medicaid Services (CMS) Public Agenda Payment and Coding Determinations for Drugs/Biologicals/Radiopharmaceuticals/ Radiologic Imaging Agents
Thursday, May 11, 2006, 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.

AGENDA ITEM #1
Attachment #06.127
Request to establish a code for I-125 Radionuclide/Brachytherapy Solution, per 1 mL, trade name: Iotrex®.

AGENDA ITEM #2
Attachment #06.52
Request to **discontinue** J7317 "Sodium Hyaluronate, per 20 to 25 mg Dose for Intra-Articular Injection" and establish two new codes differentiated based on molecular weight for Sodium Hyaluronate, trade names: Hyalgan® and Supartz. Requester also suggests that, in general, CMS assign codes to distinguish sodium hyaluronates based on molecular weight and dosage per injection.

AGENDA ITEM #3
Attachment #06.57
Request to establish a code for High Molecular Weight Hyaluronan, trade name: ORTHOVISC®.

AGENDA ITEM #4
Attachment #06.139
Request to establish a code for Sodium Hyaluronan 1%, trade name: SUPARTZ.

AGENDA ITEM #5
Attachment #06.39
Request to establish a code for 1% sodium hyaluronate, trade name: EUFLEXXA™.

AGENDA ITEM #6
Attachment #06.16
Request to establish a code for an antifungal agent, trade name: Eraxis.

AGENDA ITEM #7
Attachment #06.20
Request to establish a code for micafungin sodium, trade name: Mycamine™.

AGENDA ITEM #8
Attachment #06.43
Request to revise the dose unit of existing code J7188 "von Willebrand factor complex, human, per IU" from per "IU" to "RC_O:IU".

AGENDA ITEM #9
Attachment #06.58
Request to modify the short descriptor language of existing code J9264 "Injection, paclitaxel protein-bound particles per 1 mg" from "paclitaxel, injection" to differentiate it from the short descriptor for code J9265. Currently, the short descriptors of these 2 codes are identical. Trade name: ABRAXANE® for Injectable Suspension.

AGENDA ITEM #10
Attachment #06.87
Request to establish a "J" code for Acellular Dermal Tissue Matrix, trade name: PriMatrix™, Dermal Repair Scaffold.

AGENDA ITEM #11
Attachment #06.97
Request to establish a new and unique code for Micronized Acellular Soft-Tissue Scaffold, trade name: GRAFTJACKET® XPRESS FLOWABLE SOFT-TISSUE SCAFFOLD.

AGENDA ITEM #'s 12-13

AGENDA ITEM #12
Attachment #06.118
Request to establish 4 codes; one for each of 4 sizes of Porous Collagen-Glycosaminoglycan Matrix Wound Dressing, trade name: Integra™ Matrix Wound Dressing (IMWD).

AGENDA ITEM #13
Attachment #06.123
Request to establish 4 new codes; one for each of the 4 sizes of Collagen Glycosaminoglycan Bilayer Matrix CGBM), trade name: Integra Dermal Regeneration Template (DRT) and Integra™ Bilayer Matrix Wound Dressing (BMWD).

AGENDA ITEM #14
Attachment #06.119
Request to establish a code for Cryopreserved amniotic membrane prosthetic conformer, consisting of cryopreserved human amniotic membrane tissue attached to an acrylic resin ring, trade name: The ProKera™.

AGENDA ITEM #15
Attachment #06.134
Request to establish a code for Immune Globulin Subcutaneous (Human), trade name: Vivaglobin®.

AGENDA ITEM #16
Attachment #06.138
Request to establish a "J" code for Immune Globulin Intravenous [Human], 10% Caprylate/Chromatography Purified, trade name: GAMUNEX®.

AGENDA ITEM #'s 17-18

AGENDA ITEM #17
Attachment #06.53
Request to establish a code for Rh_0(D) Immune Globulin Intravenous (Human), trade name: WinRho® SDF Liquid, Rh_0(D) Immune Globulin Intravenous (Human)

AGENDA ITEM #18
Attachment #06.54
Request to establish a "J" code for Antihemophilic Clotting Factor (Recombinant), Plasma/Albumin Free Method (r-AHF-PFM) Biologic, trade name: ADVATE™ rAHF-PFM.

Meeting Agenda Item #1
May 11, 2006
HCPCS Request #06.127

Topic/Issue:
Request to establish a code for I-125 Radionuclide/Brachytherapy Solution, per 1 mL, trade name: Iotrex®.

Background/Discussion:
According to the requester, Iotrex is a liquid radiotherapy solution of organically bound ^{125}I. Iotrex is infused into a special catheter to deliver site-specific intra-cavitary radiation therapy (brachytherapy) to patients following resection of a malignant brain tumor while minimizing exposure to healthy tissue. The applicant suggests that existing code C2632 BRACHYTHERAPY SOLUTION, IODINE-125, PER MCI be replaced with a "permanent" code, to enable billing to non-Medicare insurers. Iotrex is available in single use vials and the typical dose will consist of 1-3 vials per patient, depending on the size of the tumor and the prescribed dose of radiation. The dose must be drawn into a syringe for injection into the patient. Requester suggested language**:** AXXXX "Iotrex I-125 radionuclide, radiotherapy, per 1 mL single-use vial"

CMS HCPCS Workgroup Preliminary Decision:
No insurer identified a national program operating need to create a new code to identify this product. When used during an inpatient procedure, it is included in the DRG, and not separately payable. For Medicare, when used in HOPPS, code C2632 may be used. This product is generally not used in a physician's office setting. For coding guidance for private insurance, contact the individual insurance contractor. For coding guidance for Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. While "C" codes may be used primarily to identify items on Medicare claims, they are not exclusively for use by Medicare. Non-Medicare insurers may assign a product to a "C" code if they deem appropriate.

Meeting Agenda Item #2
May 11, 2006
HCPCS Request #06.52

Topic/Issue:
Request to **discontinue** J7317 "Sodium Hyaluronate, per 20 to 25 mg Dose for Intra-Articular Injection" and establish two new codes differentiated based on molecular weight for Sodium Hyaluronate, trade names: Hyalgan® and Supartz. Requester also suggests that, in general, CMS assign codes to distinguish sodium hyaluronates based on molecular weight and dosage per injection.

Background/Discussion:
According to the requester, Hyalgan is used for the treatment of pain in osteoarthritis of the knee (a painful disease that can also cause stiffness and limitation of motion in the knee joint) in patients who have failed to respond adequately to conservative nonpharmacologic therapy, and to simple analgesics, e.g., acetaminophen. Hyalgan is administered by intra-articular injection in a 20mg dose. Intra-articular administration of Hyalgan into arthritic knees leads to an increase of the viscoelasticity of the synovial fluid. A treatment cycle consists of five injections given at weekly intervals. Some patients may experience benefit with three injections given at weekly intervals. This has been noted in studies reported in the literature in which patients treated with three injections were followed for 60 days. Hyalgan is supplied as a sterile, non-pyrogenic solution in 2 mL vials or 2 mL pre-filled syringes, both of which contain 20 mg of Hyalgan. According to the applicant, code J7317 is not adequate because it applies to two single-source products, Hyalgan and Supartz. Requester suggested language: JXXXX – "Hyaluronate sodium/hyaluronate sodium derivative of midpoint molecular weight 500-699 kDa, for intra-articular injection, per 20 mg dose" [for Hyalgan] and JXXXX – "Hyaluronate sodium/hyaluronate sodium derivative of midpoint molecular weight 700-1199 kDa, for intra-articular injection, per 25 mg dose" [for Supartz].

CMS HCPCS Workgroup Preliminary Decision:
In reviewing applications and input received from manufacturers of 5 products the market in the U.S. today, CMS determined that each of these products share the same biologic category (hyaluronan or derivative), clinical indication (intra-articular injection in patients with osteoarthritis) and the same product classification by the FDA (Class III Device). The documentation submitted does not demonstrate any significant therapeutic distinction (such as superior clinical outcomes) between any of the products based on there results of clinical trails as reported in journal articles published in peer-reviewed medical literature. Since there are no significant therapeutic distinctions between any of these products, it is appropriate to identify each of these products using a single code. The Workgroup's preliminary coding recommendation is to establish a single new code: JXXXX "Hyualuronan (Sodium Hualuronate) or Derivative, Intra-Articular Injection, per Injection" and to discontinue the two existing codes: J7317 "Sodium Hyaluronate, per 20 to 25 mg dose for intra-articular injection" and J7320 "Hylan G-F 20, 16 mg, for Intra-

Articular Injection". We also considered keeping the existing 2 codes and not establishing a new code, i.e., maintaining J7320 for hyaluronan derived products and J7317 for all other natural hyaluronans. This preserves the current distinction between a chemically altered form of hyaluronan and the natural sodium hyaluronante products. It also allows for possible future modifications that are derived from the natural sources of hyaluronan. We would appreciate comments on both scenarios.

Meeting Agenda Item #3
May 11, 2006
HCPCS Request #06.57

Topic/Issue:
Request to establish a code for High Molecular Weight Hyaluronan, trade name: ORTHOVISC®.

Background/Discussion:
According to the requester, ORTHOVISC® is a high molecular weight ultra-pure natural Hyaluronan dissolved in physiological saline. It is used in the treatment of pain due to osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics. ORTHOVISC® is a viscous (thick) sterile mixture made from highly purified Hyaluronan from rooster combs. High amounts of hyaluronan are naturally found within joint spaces and act as a lubricant and shock absorber to support proper joint function. Osteoarthritis may be associated with quantitative and qualitative changes in hyaluronan within the joint space. Intra-articular ORTHOVISC® works by physical action (elastoviscosity) rather than chemical action and is therefore classified by the FDA as a device rather than a drug. However, the FDA assigned a National Drug Code to ORTHOVISC®. **Requester suggested language:** J732X "High molecular weight hyaluronan per 30 mg dose for intra-articular injection".

CMS HCPCS Workgroup Preliminary Decision:
In reviewing applications and input received from manufacturers of 5 products the market in the U.S. today, CMS determined that each of these products share the same biologic category (hyaluronan or derivative), clinical indication (intra-articular injection in patients with osteoarthritis) and the same product classification by the FDA (Class III Device). The documentation submitted does not demonstrate any significant therapeutic distinction (such as superior clinical outcomes) between any of the products based on there results of clinical trails as reported in journal articles published in peer-reviewed medical literature. Since there are no significant therapeutic distinctions between any of these products, it is appropriate to identify each of these products using a single code. The Workgroup's preliminary coding recommendation is to establish a single new code: JXXXX "Hyualuronan (Sodium Hualuronate) or Derivative, Intra-Articular Injection, per Injection" and to discontinue the two existing codes: J7317 "Sodium Hyaluronate, per 20 to 25 mg dose for intra-articular injection" and J7320 "Hylan G-F 20, 16 mg, for Intra-Articular Injection". We also considered keeping the existing 2 codes and not establishing a new code, i.e., maintaining J7320 for hyaluronan derived products and J7317 for all other natural hyaluronans. This preserves the current distinction between a chemically altered form of hyaluronan and the natural sodium hyaluronante products. It also allows for possible future modifications that are derived from the natural sources of hyaluronan. We would appreciate comments on both scenarios.

Meeting Agenda Item #4
May 11, 2006
HCPCS Request #06.139

Topic/Issue:
Request to establish a code for Sodium Hyaluronan 1%, trade name: SUPARTZ.

Background/Discussion:
According to the requester, SUPARTZ is a solution made up of highly purified, sodium hyaluronate (hyaluronan). Hyaluronan is a natural chemical found in the body and is in particularly high concentrations in joint tissues and in the fluid (synovial fluid) that fills the joints. Hyaluronan is present in all vertebrates and is chemically identical irrespective of the source species. Hyaluronan acts like a lubricant and shock absorber in synovial fluid of a healthy joint. Osteoarthritis (OA) reduces a person's synovial fluid's ability to protect and lubricate the joint. SUPARTZ is a joint fluid therapy (JFT) used for the treatment of pain in osteoarthritis of the knee in patients who have failed to get adequate relief from simple pain killers or from exercise and physical therapy. SUPARTZ joint fluid therapy (2.5ml) is administered by single application arthrocentesis once a week (1 week apart) for a total of 5 injections. SUPARTZ JFT is indicated for the treatment of pain in OA of the knee in patients who have failed to respond adequately to conservative non-pharmaceologic therapy and simple analgesics, e.g., acetaminophen. The applicant suggests that HCPCS codes should distinguish between Sodium Hyaluronate products so that differences in safety profiles can be monitored. Applicant's suggested language for requested new code**:** JXXXX "ultrapure sodium hyaluronate (hyaluronan)".

CMS HCPCS Workgroup Preliminary Decision:
In reviewing applications and input received from manufacturers of 5 products the market in the U.S. today, CMS determined that each of these products share the same biologic category (hyaluronan or derivative), clinical indication (intra-articular injection in patients with osteoarthritis) and the same product classification by the FDA (Class III Device). The documentation submitted does not demonstrate any significant therapeutic distinction (such as superior clinical outcomes) between any of the products based on there results of clinical trails as reported in journal articles published in peer-reviewed medical literature. Since there are no significant therapeutic distinctions between any of these products, it is appropriate to identify each of these products using a single code. The Workgroup's preliminary coding recommendation is to establish a single new code: JXXXX "Hyualuronan (Sodium Hualuronate) or Derivative, Intra-Articular Injection, per Injection" and to discontinue the two existing codes: J7317 "Sodium Hyaluronate, per 20 to 25 mg dose for intra-articular injection" and J7320 "Hylan G-F 20, 16 mg, for Intra-Articular Injection". We also considered keeping the existing 2 codes and not establishing a new code, i.e., maintaining J7320 for hyaluronan derived products and J7317 for all other natural hyaluronans. This preserves the current distinction between a chemically altered form of hyaluronan and the natural sodium hyaluronante products. It

also allows for possible future modifications that are derived from the natural sources of hyaluronan. We would appreciate comments on both scenarios.

Meeting Agenda Item #5
May 11, 2006
HCPCS Request #06.39

Topic/Issue:
Request to establish a code for 1% sodium hyaluronate, trade name: EUFLEXXA™.

Background/Discussion:
According to the requester, EUFLEXXA™ is a viscosupplement for the treatment of pain due to osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen). EUFLEXXA™ is a viscoelastic, sterile solution of highly purified, high molecule weight hyaluronan in phosphate-buffered saline extracted by biological fermentation rather than avian sources. EUFLEXXA™ is administered via intra-articular injection into the knee using a pre-filled syringe. It is the only product approved on the basis of a head-to-head clinical trial against the market leader, Synvisc. The pivotal study demonstrated statically significant and clinically important pain relief ($P<0.0001$) with a greater percentage of EUFLEXXA™ treated patients (63%) symptom-free compared to Synvisc treated patients (52%) ($P=0.038$). Requester suggested language: "20mg highly purified hyaluronan derived from biological fermentation".

CMS HCPCS Workgroup Preliminary Decision:
In reviewing applications and input received from manufacturers of 5 products the market in the U.S. today, CMS determined that each of these products share the same biologic category (hyaluronan or derivative), clinical indication (intra-articular injection in patients with osteoarthritis) and the same product classification by the FDA (Class III Device). The documentation submitted does not demonstrate any significant therapeutic distinction (such as superior clinical outcomes) between any of the products based on there results of clinical trails as reported in journal articles published in peer-reviewed medical literature. Since there are no significant therapeutic distinctions between any of these products, it is appropriate to identify each of these products using a single code. The Workgroup's preliminary coding recommendation is to establish a single new code: JXXXX "Hyualuronan (Sodium Hualuronate) or Derivative, Intra-Articular Injection, per Injection" and to discontinue the two existing codes: J7317 "Sodium Hyaluronate, per 20 to 25 mg dose for intra-articular injection" and J7320 "Hylan G-F 20, 16 mg, for Intra-Articular Injection". We also considered keeping the existing 2 codes and not establishing a new code, i.e., maintaining J7320 for hyaluronan derived products and J7317 for all other natural hyaluronans. This preserves the current distinction between a chemically altered form of hyaluronan and the natural sodium hyaluronante products. It also allows for possible future modifications that are derived from the natural sources of hyaluronan. We would appreciate comments on both scenarios.

Meeting Agenda Item #6
May 11, 2006
HCPCS Request #06.16

Topic/Issue:
Request to establish a code for an antifungal agent, trade name: Eraxis.

Background/Discussion:
According to the requester, Eraxis is an intravenously infused antifungal. It is a semi-synthetic echinocandin with activity against a range of fungi. It selectively inhibits glucan synthase, an enzyme present in fungal cells. This results in the inhibition of the formation of 1,3-β-D-glucan, an essential component of the fungal cell wall, and production of osmotically fragile fungal cells that are easily lysed. Anidulafungin 50mg is supplied in a single-use vial of sterile, lyophilized, preservative-free powder. The companion single-use diluent vial contains 15mL of 20 percent ethanol in water for injection. For candidemia and other forms of invasive candidiasis, a single 200mg loading dose should be administered on Day 1, followed by 100mg daily thereafter. Duration of treatment should be based on the patient's clinical response. Requester's suggested language**:** JXXXX "Anidulafungin, 50mg".

CMS HCPCS Workgroup Preliminary Decision: Establish new code JXXXX "INJECTION, ANIDULAFUNGIN, 1MG"

Meeting Agenda Item #7
May 11, 2006
HCPCS Request #06.20

Topic/Issue:
Request to establish a code for micafungin sodium, trade name: Mycamine™.

Background/Discussion:
According to the requester, Myacamine is a member of a new class of antifungal agents, the echinocandins, which inhibit cell-wall synthesis. It was approved for the treatment of patients with esophageal candidiasis, and is a prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplantation. Mycamine is a sterile, lyophilized product for intravenous (IV) infusion that contains micafungin sodium. Micafungin sodium is a semisynthetic lipopeptide synthesized by a chemical modification of a fermentation product of Coleophoma empetri F-11899. Micafungin inhibits the synthesis of 1,3-β-D-glucan, an integral component of the fungal cell wall. The recommended daily dose for the treatment of esophageal candidiasis is 150mg of Mycamine per day and for prophylaxis of Candida infections of hematopoietic stem cell transplant recipients is 50mg per day. The base dose of Mycamine is 50mg. Mycamine is administered by intravenous infusion over the period of one hour. Requester suggested language: JXXXX – "Injection, micafungin sodium, 50mg".

CMS HCPCS Workgroup Preliminary Decision: Establish new code JXXXX "INJECTION, MICAFUNGIN SODIUM, 1MG"

Meeting Agenda Item #8
May 11, 2006
HCPCS Request #06.43

Topic/Issue:
Request to revise the dose unit of existing code J7188 "von Willebrand factor complex, human, per IU" from per "IU" to "RC_O:IU".

Background/Discussion:
According to the requester, antihemophilic Factor/von Willebrand Factor Complex (Human), Dried, Pasteurized, Humate-P® is a stable, purified, sterile, lyophilized concentrate of Antihemophilic Factor (Human) and von Willebrand Factor (VWF) (Human) to be administered by an intravenous route in the treatment of patients with classical hemophilia (Hemophilia A) and von Willebrand disease (vWD). It is indicated in adult patients for treatment and prevention of bleeding in hemophilia A and in adult and pediatric patients for treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand disease, and in mild and moderate von Willebrand disease where use of desmorpressin is known or suspected to be inadequate. According to the requester, the important criterion for a patient with von Willebrand's Disease is to know how much functional von Willebrand factor is being administered.

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue existing code J7188

2) Establish new code JXXXX "Injection, von Willebrand factor complex, human, Ristocetin Cofactor 500 IU VWF:RC_O.

Meeting Agenda Item #9
May 11, 2006
HCPCS Request #06.58

Topic/Issue:
Request to modify the short descriptor language of existing code J9264 "Injection, paclitaxel protein-bound particles per 1 mg" from "paclitaxel, injection" to differentiate it from the short descriptor for code J9265. Currently, the short descriptors of these 2 codes are identical. Trade name: ABRAXANE® for Injectable Suspension.

Background/Discussion:
According to the requester, ABRAXANE® is the first in a novel class of compounds combining human albumin with an active pharmaceutical agent (paclitaxel) in the nanoparticle state. The FDA recognized that ABRAXANE has qualities that differentiate it from the traditional paclitaxel products and required a black box warning on the product insert that reinforces the differentiation of the product. The pertinent parts of this warning are as follows: An albumin form of paclitaxel may substantially affect a drug's functional properties relative to those of drug in solution. DO NOT SUBSTITUTE FOR OR WITH OTHER PACLITAXEL FORMULATIONS. The requester is concerned that the short descriptor that has been assigned to J9264 is identical to the code for traditional forms of paclitaxel, J9265. This could create the impression that these products are interchangeable. **Requester suggested short descriptor language:** J9264 "paclitaxel protein-bnd prtcls".

CMS HCPCS Workgroup Preliminary Decision:
Revise the short description of code J9264 to read: "Paclitaxel, protein-bound" and revise the short descriptor of code J9265 to read: "Paclitaxel non-protein bound". Note: In general, short descriptor language is not intended to uniquely identify products and does not always distinguish between similar products, or products of different strengths. Therefore, use of short descriptors to identify items for billing could lead to inaccurate billing. Only long descriptors should be used to determine the appropriate code to report on a claim.

Meeting Agenda Item #10
May 11, 2006
HCPCS Request #06.87

Topic/Issue:
Request to establish a "J" code for Acellular Dermal Tissue Matrix, trade name: PriMatrix™, Dermal Repair Scaffold.

Background/Discussion:
According to the requester, PriMatrix™ Dermal Repair Scaffold is an acellular dermal tissue matrix used in the management of wounds. PriMatrix™ is a dermal (substitute) product of non-human origin originating from fetal bovine dermis and is processed to remove metabolically active elements. Essentially, it is the non-human equivalent of products described by code J7344. Although J7341 describes dermal (substitute) tissue of non-human origin, it is specific to those with metabolically active elements. J7343 describes dermal and epidermal (substitute) tissue of non-human origin without metabolically active elements. Despite this code describing non-human tissue without metabolically active elements, it still cannot be applied since it is specific to an implant that is both epidermal and dermal. Requester suggested language: JXXXX - "Dermal (substitute) tissue of non-human origin, with or without bioengineered or processed elements, without metabolically active elements, per sq cm".

CMS HCPCS Workgroup Preliminary Decision:
Establish JXXXX DERMAL (SUBSTITUTE) TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER.

Meeting Agenda Item #11
May 11, 2006
HCPCS Request #06.97

Topic/Issue:
Request to establish a new and unique code for Micronized Acellular Soft-Tissue Scaffold, trade name: GRAFTJACKET® XPRESS FLOWABLE SOFT-TISSUE SCAFFOLD.

Background/Discussion:
According to the requester, GRAFTJACKET® XPRESS Flowable Soft-Tissue Scaffold is a micronized (finely ground) decellularized soft tissue scaffold indicated for the repair or replacement of damaged or inadequate integumental tissue, specifically deep, dermal wounds that exhibit tunneling, and extension from the wound base that may extend deep into the tendon and bone, which are difficult to access. GRAFTJACKET® XPRESS is regulated as human tissue for transplantation by the FDA's Center for Biologics Evaluation and Research. Wright Medical is applying again in 2006 for a unique HCPCS "J" code because 1) currently it does not have such a billing code; 2) it would ensure Medicare patients access to this innovative biologic in a cost-effective setting of care – the physician office; 3) it demonstrates superior clinical results – clinical case studies show that chronic foot ulcers with tunnels treated with GRAFTJACKET® XPRESS had complete depth filling within three weeks – new clinical outcomes information for this product is presented in this application; 4) it fulfills an unmet clinical need for the treatment of chronic wounds that have sinus cavities – currently, the GRAFTJACKET® XPRESS is the only syringe-delivered graft material commercially available to treat chronic, sinus cavity wounds; 5) it provides cost savings to Medicare – the current alternative to treatment with GRAFTJACKET® XPRESS results in a cycle of partial healing and degradation of wound or more extensive surgical procedures, which could present higher costs for the Medicare program; and 6) updated sales data for this product are provided in this application. Requester suggested language: Jxxxx - "Acellular dermal soft-tissue scaffold gel, per 1 cc".

CMS HCPCS Workgroup Preliminary Decision:

1) Discontinue J7350 DERMAL (SUBSTITUTE) TISSUE OF HUMAN ORIGIN, INJECTABLE, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, BUT WITHOUT METABOLIZED ACTIVE ELEMENTS, PER 10 MG; and crosswalk to new J code.
2) Establish JXXXX DERMAL (SUBSTITUTE) TISSUE OF HUMAN ORIGIN, INJECTABLE, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, BUT WITHOUT METABOLICALLY ACTIVE ELEMENTS, 1CC.

The predicate product for J7350 is micronized acellular dermal tissue matrix. One cc unit of measure accommodates both products. Applicant has not presented evidence-based medical studies that would support claims of superior clinical outcome as a result of use of this product, when compared with other products currently categorized at J7350.

Meeting Agenda Item #12
May 11, 2006
HCPCS Request #06.118

Topic/Issue:
Request to establish 4 codes; one for each of 4 sizes of Porous Collagen-Glycosaminoglycan Matrix Wound Dressing, trade name: Integra™ Matrix Wound Dressing (IMWD).

Background/Discussion:
According to the requester, the Integra™ Matrix Wound Dressing (IMWD) consists of the dermal replacement layer of the DRT and BMWD. This dermal replacement layer is a porous matrix of fibers consisting of purified undenatured bovine collagen and chondroitin-6-sulfate with an average pore size between 70 and 200 μm and a void volume greater than 99%. The matrix is crosslinked with aqueous glutaraldehyde. The biodegradable matrix provides a scaffold for cellular invasion and capillary growth. The IMWD is normally used in conjunction with DRT or the BMWD for the surgical treatment of full thickness traumatic skin wounds in order to obtain a thicker dermal tissue replacement or for deeply excised wounds in order to fill in deeper parts of the wound and create a more level surface. According to the applicant, IMWD is not described by code J7343 "DERMAL AND EPIDERMAL, (SUBSTITUTE) TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQ CM", because IMWD does not have an epidermal layer. It is also not described by J7341 "DERMAL (SUBSTITUTE) TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITH METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER", because IMWD does not include metabolically active elements. Requester suggested language:
JXXXX "ACELLULAR DERMAL REPLACEMENT, 25 SQ CM"
JXXXX "ACELLULAR DERMAL REPLACEMENT, 125 SQ CM"
JXXXX "ACELLULAR DERMAL REPLACEMENT, 250 SQ CM"
JXXXX "ACELLULAR DERMAL REPLACEMENT, 500 SQ CM"

CMS HCPCS Workgroup Preliminary Decision:
Establish JXXXX DERMAL (SUBSTITUTE) TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER. No insurer identified a national program operating need to create size-dependent codes for this product. Providers can designate square centimeter multiples in the "units" column on the claim form. Inquiries regarding pricing are not within the purview of the HCPCS code set maintainers, and should be submitted directly to insurers.

Meeting Agenda Item #13
May 11, 2006
HCPCS Request #06.123

Topic/Issue:

Request to establish 4 new codes; one for each of the 4 sizes of Collagen Glycosaminoglycan Bilayer Matrix CGBM), trade name: Integra Dermal Regeneration Template (DRT) and Integra™ Bilayer Matrix Wound Dressing (BMWD).

Background/Discussion:

According to the requester, Integra Dermal Regeneration Template (DRT) and Integra™ Bilayer Matrix Wound Dressing (BMWD) are identical in composition and clinical procedure. CGBM is a bilayer system comprising a dermal replacement layer and a temporary epidermal substitute layer. The dermal replacement layer is a porous matrix of fibers consisting of purified undenatured bovine collagen and chondroitin-6-sulfact with an average pore size between 70 and 200 μm and a void volume greater than 99%. The temporary epidermal substitute layer is made of silicone 200 to 300 μm thick and it firmly adheres to the dermal replacement layer. The bilayer matrix is capable of holding a suture or staple with sufficient strength to affix it to a wound bed and is highly "drapable" to enable it to adhere to an irregular or convex wound bed. CGBM is used as an alternative to a conventional skin autograft in skin replacement surgery to repair a full-thickness or deep partial thickness skin wound. Like autograft, CGBM can accomplish wound healing by first intention. CGBM creates an immediate wound closure followed by regeneration of histologically and functionally normal skin. According to the applicant, Integra CGBM and BMWD are currently assigned to code J7343 "DERMAL AND EPIDERMAL, (SUBSTITUTE) TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQ CM". However; because the existing ASP calculation for this code averages prices to arrive at a single "per sq cm" price, this methodology causes Medicare payments to hospitals for the small sized products to be insufficient to cover the hospitals' acquisition cost and payments for larger sizes to be substantially greater than acquisition cost. Requester suggested language for the requested 4 new codes:

JXXXX "ACELLULAR DERMAL REPLACEMENT, 25 SQ CM"
JXXXX "ACELLULAR DERMAL REPLACEMENT, 125 SQ CM"
JXXXX "ACELLULAR DERMAL REPLACEMENT, 250 SQ CM"
JXXXX "ACELLULAR DERMAL REPLACEMENT, 500 SQ CM"

CMS HCPCS Workgroup Preliminary Decision:

Existing code J7343 DERMAL AND EPIDERMAL, (SUBSTITUTE) TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER adequately identifies the products that are the subject of this application. The products can be billed in sq. cm. multiples, therefore it is unnecessary to establish distinct codes based on product size. Coding is not based on pricing. Inquiries regarding fee schedules are not within the purview of HCPCS code set maintainers, and should be submitted directly to insurers.

Meeting Agenda Item #14
May 11, 2006
HCPCS Request #06.119

Topic/Issue:
Request to establish a code for Cryopreserved amniotic membrane prosthetic conformer, consisting of cryopreserved human amniotic membrane tissue attached to an acrylic resin ring, trade name: The ProKera™.

Background/Discussion:
According to the requester, the ProKera™ is a prosthetic device that secures cryopreserved amniotic membrane tissue to the surface of the eye without the need for sutures. The ProKera™ is a corneal amniotic membrane insert, consisting of amniotic membrane preserved through cryopreservation and attached to an acrylic resin ring. The ProKera™ is intended for use in eyes in which the ocular surface cells have been damaged, or underlying stroma is inflamed and scarred. The ring component of the ProKera™ is made of acrylic resin known as polymethylmetracrylate (PMMA), the same material used to make hard contact lenses. The ProKera™ consists of two PMMA rings held together by a snapping mechanism to create one device. The rings are sized so that one ring fits inside of the other ring. The amniotic membrane is stretched over the inner "skirt" ring and held in place by fastening the outer or "snapping" ring over it. The amniotic membrane is sized and cut so that it is secured between the two rings, and also extends over the edges of the skirt. Thus, when it is inserted into the eye, the membrane contacts the patient from both sides of the device – both the ocular surface and the inner eyelid are in contact with the membrane. The ProKera™ eliminates the need for sutures to hold the amniotic membrane in place. According to the applicant, there is no existing code that describes the Prokera device, and miscellaneous codes do not precisely describe the device or pay adequately. Requester suggested language: "Cryopreserved amniotic membrane prosthetic conformer"

CMS HCPCS Workgroup Preliminary Decision:
Existing code V2790 "AMNIOTIC MEMBRANE FOR SURGICAL RECONSTRUCTION, PER PROCEDURE" adequately describes this device and is available for assignment by any insurer. Use of miscellaneous codes is inappropriate. Inquiries regarding fees associated with V2790 are not within the purview of HCPCS code set maintainers, and should be submitted to the individual insurer.

Meeting Agenda Item #15
May 11, 2006
HCPCS Request #06.134

Topic/Issue:
Request to establish a code for Immune Globulin Subcutaneous (Human), trade name: Vivaglobin®.

Background/Discussion:
According to the requester, Vivaglobin® is a highly purified immune globulin product, made from human plasma. Vivaglobin® contains the antibody immunoglobulin G (IgG), which is found in the blood of healthy individuals to help combat bacteria and viruses. Vivaglobin® helps rid the body of the antigens. This is particularly important for patients with primary immune deficiency diseases, which can involve frequent life-threatening infections and debilitating illnesses. While these patients may also obtain this antibody through products administered intravenously or intramuscularly, not all patients are suited for these modes of administration and can have severe anaphylactoid reactions.

Vivaglobin® is the first product approved for subcutaneous administration, and may be particularly important for this patient population. Dosing for Vivaglobin® is 100mg to 200mg per kg body weight, administered subcutaneously on a weekly basis via an ambulatory infusion pump. Dosing is adjusted over time to achieve the desired clinical response and serum IgG levels. Vivaglobin® is approved for marketing in 3, 10 and 20 ml vials (160mgIgG/ml).

CMS HCPCS Workgroup Preliminary Decision:
Establish new code JXXXX "INJECTION, IMMUNE GLOBULIN, SUBCUTANEOUS,500MG".

Meeting Agenda Item # 16
May 11, 2006
HCPCS Request #06.138

Topic/Issue:
Request to establish a "J" code for Immune Globulin Intravenous [Human], 10% Caprylate/Chromatography Purified, trade name: GAMUNEX®.

Background/Discussion:
According to the requester, GAMUNEX® is indicated as replacement therapy for primary immunodeficiency (PI) states in which severe impairment of antibody forming capacity has been shown, such as congenital agammaglobulinemia, common variable immunodeficiency, X-linked immunodeficiency with hyper IgM, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. GAMUNEX® is indicated in idiopathic thrombocytopenic purpura (ITP) to rapidly raise platelet counts to prevent bleeding or to allow a patient with ITP to undergo surgery.
In the treatment of PI, GAMUNEX® proved to be effective in preventing infection in patients. In the treatment of ITP, the mechanism of action of high doses of immunoglobulins has not been fully elucidated. Several lines of evidence suggest that Fc-receptor blockage of phagocytes as well as down regulation of auto-reactive B-cells by anti-idiotypic antibodies provided by GAMUNEX® may constitute the main mechanisms of action. GAMUNEX solution is administered by intravenous infusion only. It is recommended that GAMUNEX initially be infused at a rate of 0.01 mL/kg per minute for the first 30 minutes. If well tolerated, the rate may be gradually increased to a maximum of 0.08 mL/kg per minute. The applicant claims that differences across IVIG products in terms of concentration, osmolarity, pH, and composition can impact tolerability and efficacy, especially for patients with risk factors, and requests a code distinction on the basis of the purification process used in manufacturing GAMUNEX. Applicant suggested language for requested new code**:** JXXXX "Injection, Immune Globulin Intravenous, Non-lyophilized, Caprylate/Chromatography Purified (IGIV-C)".

CMS HCPCS Workgroup Preliminary Decision:
Existing code J1567 "INJECTION IMMUNE GLOBULIN, INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG" adequately describes the product that is the subject of this request. HCPCS codes represent categories of similar products. Selection of products within a code category for individual patients is the responsibility of the treating physician. No insurer identified a national program operating need to differentiate this product, to implement their policies differently or adjudicate claims differently based on the purification process used in manufacture.

Meeting Agenda Item #17
May 11, 2006
HCPCS Request #06.53

Topic/Issue:
Request to establish a code for Rh_0(D) Immune Globulin Intravenous (Human), trade name: WinRho® SDF Liquid, Rh_0(D) Immune Globulin Intravenous (Human)

Background/Discussion:
According to the requester, WinRho® SDF Liquid is derived from human plasma and administered intravenously for the treatment of immune thrombocytopenic purpura (ITP), which is a bleeding disorder caused by an abnormally low level of platelets. In ITP, the immune system produces antibodies against platelets causing their premature destruction. Platelets are components of the blood that are necessary for blood to clot properly. Individuals who suffer from ITP may have symptoms such as bruising on skin and gums, nosebleeds, or mucosal bleeding. The most serious consequence with ITP is intracranial hemorrhage. WinRho® SDF Liquid is indicated for the treatment of nonsplenectomized (spleen has not been surgically removed), Rh_0(D)-positive (those with A,B,AB and O positive blood types) children with chronic or acute ITP, adults with chronic ITP, and children and adults with ITP secondary to HIV infection in clinical situations requiring an increase in platelet count to prevent excessive hemorrhage. WinRho SDF Liquid is a second generation sterile, liquid gamma globulin (IgG) fraction containing antibodies to the Rho(D) antigen (Dantigen). The first generation Rho(D) Immune Globulin Intravenous (Human) was introduced into the United States as a lyophilized powder.

CMS HCPCS Workgroup Preliminary Decision:
Existing code J2792 "INJECTION, RHO D IMMUNE GLOBULIN, INTRAVENOUS, HUMAN, SOLVENT DETERGENT, 100 IU" adequately describes this product. No insurer identified a national program operating need to establish a code to distinguish it from other products categorized at J2792. The product that is the subject of this application was not marketed in the United States at the time of application. The applicant did not present clinical studies to substantiate a claim of superior clinical outcome as a result of use of this product, when compared with other products coded at J2792.

Meeting Agenda Item #18
May 11, 2006
HCPCS Request #06.54

Topic/Issue:
Request to establish a "J" code for Antihemophilic Clotting Factor (Recombinant), Plasma/Albumin Free Method (r-AHF-PFM) Biologic, trade name: ADVATE™ rAHF-PFM.

Background/Discussion:
According to the requester, ADVATE™ rAHF-PFM is a recombinant FVIII glycoprotein indicated for the prevention and control of bleeding episodes and the perioperative management of patients with hemophilia A. Approximately 80% of hemophilia patients have hemophilia A, a congenital bleeding disorder resulting from insufficient levels of FVIII coagulation activity and characterized by a prolonged clotting time. The existing code J7192, "Factor VIII (ANTIHEMOPHILIC FACTOR, RECOMBINANT) PER I.U.", does not reflect the current state-of-the-art technology, nor does it reflect what is becoming the next advancement in the treatment of hemophilia A. The unique production of ADVATE™ rAHF-PFM is not simply a more refined purification process compared to other recombinant products on the market today. All other recombinant factor VIII products use human- or animal blood-derived additives in the cell culture medium to nourish the cells. Production of ADVATE™ rAHF-PFM uses plant components, sugars and salts to make up the culture medium. Human and animal components are never used. The advanced cell culture process, devoid of human and animal proteins, makes ADVATE™ rAHF-PFM unique and sets it apart from other recombinant FVIII products by eliminating the risk of pathogen transmission associated with the use of human and animal derived proteins. Requester suggested language**:** J7XXX "Factor VIII (antihemophilic factor, recombinant, plasma/albumin free)"

CMS HCPCS Workgroup Preliminary Decision:
Existing code J7192 "FACTOR VIII (ANTIHEMOPHILIC FACTOR, RECOMBINANT) PER I.U" adequately describes the product that is the subject of this application. No insurer identified a national program operating need to distinguish this product. Clinical information included with the application does not establish a significant clinical benefit as a result of use of this product, when compared with other products categorized at J7192.

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, 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.

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 dispenses 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 2006, the furnishing fee is $0.146 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