Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Drugs, Biologicals, and Radiopharmaceuticals
Tuesday, May 17, 2011

Introduction and Overview

Approximately 100 people attended. The agenda included 30 items.

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

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

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

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

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

In November, all requestors will be notified in writing of the final decision regarding the HCPCS code modification request(s) they submitted. At about the same time, the

HCPCS Annual Update is published at:
www.cms.hhs.gov/HCPCSReleaseCodeSets/ANHCPCS/itemdetail.asp.

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

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Drugs, Biologicals and Radiopharmaceuticals
Tuesday, May 17, 2011 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' preliminary coding decision is provided. 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#11.063
Request to establish a code for pre-storage pooled, leukocyte reduced, ABO-matched, bacteria tested platelets.

Primary Speaker: Robert Haime of Pall Medical

AGENDA ITEM #2
Attachment#11.001
Request to establish a new HCPCS Level II code for Gammaplex® Immune Globulin Intravenous (Human).

No Primary Speaker

AGENDA ITEM #3
Attachment#11.051
Request to revise the description of existing HCPCS code J1561 "INJECTION, IMMUNE GLOBULIN, (GAMUNEX), INTRAVENOUS, NON-LYOPHILIZED (E.G., LIQUID), 500 MG" to expand its use for subcutaneous administration and incorporate trade name change from Gamunex to Gamunex-C.

Primary Speaker: George Oliver of Talecris Biotherapeutics

AGENDA ITEM #4
Attachment#11.061
Request to establish a separate code for immune globulin (human), trade name: Flebogamma® 10% DIF.

No Primary Speaker

AGENDA ITEM #5
Attachment#11.018
Request to establish a code for Crotalidae Polyvalent Immune Fab (Ovine), trade name: CroFab®.

Primary Speaker: Dr. Emmanuel Mahlis of BTG International, Inc.

AGENDA ITEM #6
Attachment#11.020
Request to establish a code for Belimumab, trade name: Benlysta.

No Primary Speaker

AGENDA ITEM #7
Attachment#11.035
Request to establish a code for $Alpha_1$-Proteinase, trade name: GLASSIA.

No Primary Speaker

AGENDA ITEM #8
Attachment#11.062
Request to discontinue existing code J7184 "INJECTION, VON WILLEBRAND FACTOR COMPLEX (HUMAN), WILATE, PER 100 IU VWF:RCO" and replace it with a new code for the same product, specifying a different dose descriptor.

No Primary Speaker

AGENDA ITEM #9
Attachment#11.025
Request to establish a code for Factor XIII Concentrate (Human), trade name: Corifact™, Factor XIII Concentrate (Human).

No Primary Speaker

AGENDA ITEM #10
Attachment#11.021
Request to establish a code for cross-linked hyaluronate hydrogel, trade name: Gel-One®.

Primary Speaker: Nick Pacelli of Zimmer, Inc.

AGENDA ITEM #11
Attachment#11.033
Request to establish a single new HCPCS code to identify Denosumab marketed under trade names: Prolia® and XGEVA™.

No Primary Speaker

AGENDA ITEM #12
Attachment#11.074
Request to establish a code for alglucosidase alfa, trade name: Lumizyme®.

Primary Speaker: Dr. Timothy Miller of Genzyme Corporation

AGENDA ITEM #13
Attachment#11.026
Request to establish a code for Ipilimumab, trade name: YERVOY™.

No Primary Speaker

AGENDA ITEM #14
Attachment#11.002
Request to establish a new, product-specific HCPCS code within the J9000 range (for chemotherapy agents) for Dacogen® (decitabine) for Injection.

No Primary Speaker

AGENDA ITEM #15
Attachment#11.003
Request to establish a code in the J9000 series for eribulin mesylate for injection, trade name: HALAVEN™.

No Primary Speaker

AGENDA ITEM #16
Attachment#11.013
Request to establish a code for Cabazitaxel injection, trade name: Jevtana®.

No Primary Speaker

AGENDA ITEM #17
Attachment#11.072
Request to establish a code for Sipuleucel-T, trade name: PROVENGE®.

Primary Speaker: Kevin Cline of Dendreon

AGENDA ITEM #18
Attachment#11.005
Request to establish a code for everolimus, trade name: Zortress®.

No Primary Speaker

AGENDA ITEM #19
Attachment#11.121
Request to establish a code for hydroxyprogesterone caproate injection for intramuscular use, trade name: Makena™.

No Primary Speaker

AGENDA ITEM #20
Attachment#11.012
Request to establish a code for incobotulinumtoxinA, trade name: Xeomin®.

No Primary Speaker

AGENDA ITEM #21
Attachment#11.030
Request to establish a code for Pegloticase, trade name: KRYSTEXXA.

No Primary Speaker

AGENDA ITEM #22
Attachment#11.034
Request to establish two HCPCS codes for Ondansetron, trade name: Zuplenz.

No Primary Speaker

AGENDA ITEM #23
Attachment#11.041
Request to establish a code for Lacosamide, trade name: VIMPAT®.

No Primary Speaker

AGENDA ITEM #24
Attachment#11.050
Request to establish a code for Ceftaroline Fosamil for IV administration, trade name: Teflaro®.

No Primary Speaker

AGENDA ITEM #25
Attachment#11.123
Request to establish a code for Minocycline Hydrochloride, trade name: MINOCIN.

No Primary Speaker

AGENDA ITEM #26
Attachment#11.052
Request to establish a code for Mannitol inhalation powder, trade name: Aridol.

Primary Speaker: Andrew Ruskin of Morgan, Lewis & Bockius LLP

AGENDA ITEM #27
Attachment#11.058
Request to establish a code for a lidocaine 70 mg/tetracaine 70 mg topical patch, trade name; SYNERA®.

No Primary Speaker

AGENDA ITEM #28
Attachment#11.066
Request to establish a code for testosterone pellets for subcutaneous implantation, trade name: Testopel® Pellets.

No Primary Speaker

AGENDA ITEM #29
Attachment#11.073
Request to establish a code for acetaminophen injection for IV use, trade name: OFIRMEV™.

Primary Speaker: Dr. Robert Ang of Cadence Pharmaceuticals, Inc.

AGENDA ITEM #30
Attachment#11.119
Request to establish 2 new HCPCS codes for Baclofen injection, trade name: Gablofen®.

No Primary Speaker

HCPCS Public Meeting Agenda Item #1
05/17/2011

Attachment# **11.063**

Topic/Issue:

Request to establish a code for pre-storage pooled, leukocyte reduced, ABO-matched, bacteria tested platelets. Applicant's suggested language: "Platelets, pre-storage pooled, leukocyte reduce, ABO-matched, bacteria tested, each unit."

Background/Discussion:

The requester is the manufacturer of the proprietary system used to produce the platelets that are the subject of this application. The product is a therapeutic dose of whole blood derived platelets indicated as a replacement for depleted platelets. According to the requester, there are a number of codes for platelets, but none capture the important collective attributes (pooled ABO-matched and bacteria tested) of the platelets that are the subject of this application. These attributes confer a significant therapeutic distinction and are a unique outcome of using the Acrodose™ Systems.

CMS HCPCS Workgroup Preliminary Decision:

Existing code P9031 PLATELETS, LEUKOCYTES REDUCED, EACH UNIT adequately describes this product. A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. The American Association of Blood Banks standards require that all platelets be bacterial tested using an FDA-approved method. Platelets may be either ABO-matched or ABO-compatible.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the Workgroup's preliminary decision and reiterated the request for a new code. The speaker noted several differences between products coded at P9031 and the applicant's product. Specifically: the applicant's product represents a full therapeutic dose; it is pooled at a hospital and is a finished product, as opposed to other products in code P9031 which are pooled at a donor center and are non-culture based tested non-standard dose. The applicant’s product development process allows for all constituent PC units in the pool to be tested with a single FDA culture-based bacteria test for platelets...utilizing the "gold standard" in platelet testing methods (unlike individual PCs billed under P9031). The speaker claimed that the assignment of a unique billing code for the final pooled product will allow hospitals to bill on a consistent basis as a single dose and remove billing variability and uncertainty (e.g., hospitals need to know how many PC's the blood collection facility may have used to establish the final dose).

HCPCS Public Meeting Agenda Item #2
05/17/2011

Attachment# **11.001**

Topic/Issue:

Request to establish a new HCPCS Level II code for Gammaplex® Immune Globulin Intravenous (Human).

Background/Discussion:

According to the requester, Gammaplex is a liquid, ready to use 5% (50 mg/mL) solution of human normal immunoglobulin G (IgG) for intravenous administration. It is prepared from pooled plasma from healthy U.S. plasma donors. Gammaplex is indicated for the treatment of primary humoral immunodeficiency (PI). Gammaplex acts through a broad spectrum of opsonic and neutralizing IgG antibodies against pathogens and their toxins involving antigen binding and effector functions. The recommended dose of Gammaplex for patients with PI is 300 to 800 mg/kg (6 to 16 mL/kg), administered every 3 to 4 weeks. The dosage should be adjusted over time to achieve the desired serum through levels and clinical responses. This intravenous immunoglobulin (IVIG) is supplied in the following single-use vial sizes: 2.5 grams in 50mL, 5 grams in 100 mL and 10 grams in 200 mL. Gammaplex differs from other licensed IVIG products in several significant respects that can affect product tolerability and safety, including the following: (1) product form (liquid vs. lyophilized), (2) IgG concentration, (3) IgG stabilizers contained in this product, (4) recommended initial infusion rate (and maintenance infusion rate), and (5) virus inactivation and removal steps. Gammaplex and other IVIG products may differ also with respect to labeled indications, storage conditions, and vial fill sizes. The applicant is requesting a unique code for Gammaplex consistent with coding for similar products.

CMS HCPCS Workgroup Preliminary Decision:

Establish Jxxxx INJECTION, IMMUNE GLOBULIN, (GAMMAPLEX), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #3
05/17/2011

Attachment# **11.051**

Topic/Issue:

Request to revise the description of existing HCPCS code J1561 "INJECTION, IMMUNE GLOBULIN, (GAMUNEX), INTRAVENOUS, NON-LYOPHILIZED (E.G., LIQUID), 500 MG" to expand its use for subcutaneous administration and incorporate trade name change from Gamunex to Gamunex-C.
Applicant's suggested language: "INJECTION, IMMUNE GLOBULIN, (GAMMUNEX-C), NON-LYOPHILIZED (E.G., LIQUID), 500 MG"

Background/Discussion:

According to the requester, the trade name GAMUNEX has been changed to GAMUNEX-C. The product under the new name is labeled for both intravenous and subcutaneous administration. GAMUNEX-C is an immune globulin liquid indicated for the treatment of Primary Humoral Immunodeficiency (PI), Idiopathic Thrombocytopenic Purpura (ITP), and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). It is indicated as replacement therapy of PI states in which severe impairment of antibody forming capacity has been shown, such as congenital agammaglobulinemia, common variable immunodeficiency, and X-linked immunodeficiency with hyper IgM, Wiskott - Aldrich syndrome and severe combined immunodeficiency's. In the treatment of PI, GAMUNEX-C supplies a broad spectrum of opsonic and neutralizing IgG antibodies against bacteria, viral, parasitic, mycoplasma agents, and their toxins. In the treatment of ITP, GAMUNEX-C is indicated to rapidly raise platelet counts to prevent bleeding or allow a patient with ITP to undergo surgery. GAMUNEX-C is also indicated in the treatment of CIDP to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse. The mechanism of action in PI, ITP and CIDP has not been fully elucidated. GAMUNEX-C is supplied in single-use bottles: 1g/10mL; 2.5g/25mL; 5g/50mL; 10g/100mL; and 20g/200mL. For intravenous administration, the dose of GAMUNEX-C is 300 to 600 mg/kg body weight (3-6 mL/kg) administered every 3 to 4 weeks. For subcutaneous administration of GAMUNEX-C for PI, it is recommended that GAMUNEX-C is infused at a rate of 20 mL/hr per infusion site. Initial infusion rate is 1 mg/kg/min for PI; 1 mg/kg/min for ITP; and 2 mg/kg/min for CIDP. Following initial infusion, the infusion rate may be gradually increased to a maximum of 0.08 mL/kg per minute as tolerated. According to the requester, a revision to HCPCS code J1561 is required to reflect the name change and to remove reference to intravenous administration.

CMS HCPCS Workgroup Preliminary Decision:

1) Discontinue code J1561 INJECTION, IMMUNE GLOBULIN, (GAMUNEX), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID) 500 MG

2) Establish Jxxxx INJECTION, IMMUNE GLOBULIN, (GAMUNEX/GAMUNEX-C), NON-LYOPHILIZED (E.G., LIQUID), 500 MG

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker was appreciative of the workgroup's preliminary decision to establish a new code for Gamunex/Gamunex-C. The speaker asked for two modifications and suggested a different option that would incorporate both the CMS recommendation and the applicant's request and address "mutual objectives of improving claims submissions and processing including minimizing delays in patient treatment." Specifically: the speaker requested that code J1561 be maintained to identify Gamunex until the remaining supply is sold out or expires. The speaker also recommended that the new code identify Gamunex-C only. In general, the speaker requested separate codes to serve as alerts to differences in labeling. Gamunex C labeling does not include instructions for subcutaneous administration.

HCPCS Public Meeting Agenda Item #4
05/17/2011

Attachment# **11.061**

Topic/Issue:

Request to establish a separate code for immune globulin (human), trade name: Flebogamma® 10% DIF.

Background/Discussion:

According to the Requester, Flebogamma® 10% DIF is a liquid, room temperature intravenous immunoglobulin solution obtained from human plasma. It is intended for replacement therapy in primary (inherited) humoral immunodeficiency disorders. The usual dose of Flebogamma® DIF replacement therapy in primary humoral immunodeficiency diseases is 300 to 600 mg/kg body weight administered every 3 to 4 weeks. Doses may be adjusted over time to achieve the desired trough IgG levels and clinical response. Flebogamma® DIF is supplied in single dose vials containing 5, 10 or 20 grams of IgG as a 10% liquid solution. The requester states Flebogamma® DIF is the only IVIG product to have individually identified laser-etched vials to ensure full traceability and deter tampering. While the final formulation, excipients and primary packaging are the same for Flebogamma 5% DIF and 10% DIF with the only exception being the final protein concentration the requester claims that billing errors, particularly for Medicaid, are likely to occur without a unique HCPCS code distinguishing Flebogamma 10% DIF from Flebogamma 5% (as coded at J1572 INJECTION, IMMUNE GLOBULIN, (FLEBOGAMMA/FLEBOGAMMA DIF), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG). The requester also claims that using J1572 for 5% DIF and 10% DIF would result in substantial over or under reporting of product utilization and consequently, inaccurate Medicaid drug rebate invoicing.

CMS HCPCS Workgroup Preliminary Decision:

Existing code J1572 INJECTION, IMMUNE GLOBULIN, (FLEBOGAMMA/FLEBOGAMMA DIF), INTRAVENOUS, NON-LYOPHILIZED (E.G. LIQUID), 500 MG adequately describes the product that is the subject of this request as well as Flebogamma 5% DIF.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #5
05/17/2011

Attachment# **11.018**

Topic/Issue:

Request to establish a code for Crotalidae Polyvalent Immune Fab (Ovine), trade name: CroFab®. Applicant's suggested language: "Injection, Crotalidae Polyvalent Immune Fab (Ovine), per vial".

Background/Discussion:

According to the requester, CroFAb® is a venom-specific Fab fragment of immunoglobulin G (IgG) that is indicated for the management of patients with North American crotalidae (rattlesnake, water moccasin, copperhead) envenomation. It works by binding and neutralizing venom toxins, facilitating their redistribution away from target tissues and their elimination from the body. CroFab® is supplied as sterile, lyophilized powder. Each vial contains up to 1 gram of total protein, a maximum of 0.11 mg of mercury, and not less than the indicated number of mouse LD50 neutralizing units. Diluent is not included. Dosing is not weight-based. The initial dosage is 4 to 6 vials given intravenously. If initial control is not achieved by the first dose, an additional dose of 4 to 6 vials should be repeated until initial control is achieved. Once initial control is achieved, an additional 2 vial doses, every 6 hours, for up to 18 hours is recommended. The lowest unit of use is 1 vial. A partial vial should never be administered. According to the requester, CroFab® is currently identified by C9274 "CROTALIDAE POLYVALENT IMMUNE FAB (OVINE), 1 VIAL." A HCPCS J code is requested to enable use of the product across all potential settings.

CMS HCPCS Workgroup Preliminary Decision:

Establish Jxxxx INJECTION, CROTALIDAE POLYVALENT IMMUNE FAB (OVINE), UP TO 1 GRAM

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker thanked the workgroup for its preliminary decision to establish a J code for CroFab®. However, the speaker suggested that the dose descriptor read "per vial" rather than the proposed "up to 1 gram." The speaker commented that the amount or weight of protein in a vial may differ from batch to batch and that the section of the prescribing information describing the amount of protein refers to the filling process, not to the amount of product recommended for dosing. According to the speaker, the dose is measured in millitres. It is administered as full vials reconstituted with 10 mL sterile water and then further diluted in 250 mL normal saline, for IV infusion.

HCPCS Public Meeting Agenda Item #6
05/17/2011

Attachment# **11.020**

Topic/Issue:

Request to establish a code for Belimumab, trade name: Benlysta. Applicant's suggested language: "Belimumab for intravenous infusion, 10 mg."

Background/Discussion:

According to the requester, Benlysta is a B-lymphocyte stimulator (BLyS) - specific inhibitor indicated for reducing disease activity in adult patients with active, autoantibody-positive, systemic lupus erythamtosus who are receiving standard therapy. It blocks the binding of soluble BLyS to its receptors on B-cells to inhibit the survival of B-cells and reduce the differentiation of B-cells into immunoglobulin-producing plasma cells. The FDA cleared Benlysta with the following limitations of use: "The efficacy of Benlysta has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Benlysta has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta is not recommended in these situations." The recommended dosage regimen is 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter. Benlysta should be infused over a 1-hour period. It should not be administered as I.V. push or bolus. It is supplied as a lyophilized powder for intravenous infusion as 120 mg Belimumab in a 5-ml single-use vial and also as 400 mg Belimumab in a 20-ml single-use vial. Upon reconstitution, each single-use vial delivers 80 mg/ml Belimumab. According to the requester, there are currently no codes to adequately describe Belimumab and there are no other drugs marketed with the same active ingredient.

CMS HCPCS Workgroup Preliminary Decision:

1) New code Q2044 INJECTION, BELIMUMAB, 10 MG (eff. 7/1/2011) adequately describes the product
2) Discontinue Q2044 effective 12/31/2011
3) Establish Jxxxx INJECTION, BELIMUMAB, 10 MG (eff. 1/1/2012)
Comments are invited regarding discontinuation of Q2044 at the end of 2011 with the establishment of a Jxxxx code to replace it.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #7
05/17/2011

Attachment# **11.035**

Topic/Issue:

Request to establish a code for Alpha$_1$-Proteinase, trade name: GLASSIA. Applicant's suggested language: Alpha$_1$-Proteinase Inhibitor (Human), per 10 mg (GLASSIA).

Background/Discussion:

According to the applicant, GLASSIA is an alpha$_1$-proteinase inhibitor indicated for chronic augmentation and maintenance therapy in adults with emphysema due to congenital deficiency of alpha$_1$-proteinase inhibitor (Alpha-PI), also known as alpha - antitrypsin deficiency. Alpha$_1$-PI deficiency is a chronic, autosomal, co-dominant hereditary disorder characterized by reduced levels of Alpha$_1$-PI in the blood and lungs. Because emphysema affects many, but not all individuals with the more severe genetic variants of Alpha$_1$-PI deficiency (AAT deficiency), augmentation therapy with Alpha$_1$Proteinase Inhibitor (Human) is indicated only in patients with severe Alpha$_1$ PI deficiency that have clinically evident emphysema. The recommended dosage of GLASSIA is 60 mg/kg body weight administered once weekly by intravenous infusion. GLASSIA is supplied in a single use vial containing approximately 1 gram of functional Alpha$_1$ -PI in 50 mL of ready to use solution. Similar products are Aralast™ Baxter Healthcare; Zemaira™ CSL Behring; Prolastin® Talecris. The applicant claimed that the other Alpha¹ Proteinase Inhibitors were all approved prior to 10/01/2003. The code being billed for these products is J0256 Injection, Alpha$_1$ Proteinase Inhibitor, and 10 mg. According to the requester, Pursuant to Section 1847A of the Social Security Act, as added by the Medicare Modernization Act of 2003, GLASSIA meets the criteria to be separately priced under Medicare's ASP payment program.

CMS HCPCS Workgroup Preliminary Decision:

1) Establish Jxxxx INJECTION, ALPHA 1-PROTEINASE INHIBITOR (HUMAN), (GLASSIA), 10 MG
2) Revise code J0256 which currently reads INJECTION, ALPHA 1 - PROTEINASE INHIBITOR - HUMAN, 10 MG to instead read INJECTION, ALPHA 1 PROTEINASE INHIBITOR (HUMAN), NOT OTHERWISE SPECIFIED, 10MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #8
05/17/2011

Attachment# **11.062**

Topic/Issue:

Request to discontinue existing code J7184 "INJECTION, VON WILLEBRAND FACTOR COMPLEX (HUMAN), WILATE, PER 100 IU VWF:RCO" and replace it with a new code for the same product, specifying a different dose descriptor.

Background/Discussion:

According to the Requester, wilate® (von Willebrand Factor I, Coagulation Factor VIII concentrate [Human]) is indicated for spontaneous or trauma induced bleeding episodes in patients with severe von Willebrand Disease (VWD) and patients with mild VWD in whom the use of desmopression is known or suspected to be ineffective or contraindicated. The requester is asking CMS to invalidate the J7184 code with its dose descriptor of 100 international units and replace it with a new code using 1 I.U. as the dose descriptor, as is used in all other vWF codes. The February 5, 2010, CMS decision (CR 6811, Transmittal 1908) to revise the definition of "units" for purpose of calculating the furnishing fee has created a reimbursement disadvantage for wilate® vis a vis its competitor vWF products. Specifically, according to this requester, the furnishing fee is only fairly applied when the dose descriptor is consistent across codes for vWF products.

CMS HCPCS Workgroup Preliminary Decision:

1) Newly established code Q2041 INJECTION, VON WILLEBRAND FACTOR COMPLEX (HUMAN), WILATE, 1 I.U. VWF:RCO effective July 1, 2011 adequately describes Wilate.
2) Discontinue code J7184 INJECTION, VON WILLEBRAND FACTOR COMPLEX (HUMAN), WILATE, PER 100 IU VWF:RCO Effective December 31, 2011.
3) Discontinue code Q2041 INJECTION, VON WILLEBRAND FACTOR COMPLEX (HUMAN), WILATE, 1 I.U. VWF:RCO effective December 31, 2011
4) Establish Jxxxx INJECTION, VON WILLEBRAND FACTOR COMPLEX (HUMAN), WILATE, 1 I.U. VWF:RCO effective January 1, 2011.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #9
05/17/2011

Attachment# **11.025**

Topic/Issue:

Request to establish a code for Factor XIII Concentrate (Human), trade name: Corifact™, Factor XIII Concentrate (Human). Applicant's suggested language: "Factor XIII Concentrate, (Human) Corifact, each IU".

Background/Discussion:

According to the requester, Corifact™ is an endogenous plasma glycoprotein indicated for routine prophylactic treatment of children and adults with congenital Factor XIII deficiency. It is used to replace the missing Factor XIII and raise Factor XIII levels. Dosing, duration of dosing and frequency of administration in adults and children should be individualized based on the extent and type of bleeding history, body weight and laboratory values. Initial dose is 40 international units (IU)/kg body weight. Subsequent dosing should be guided by the most recent trough FXIII activity level, with dosing every 28 days (4 weeks) to maintain a trough FXIII activity level of approximately 5% to 20%. Doses should be given intravenously at a rate not exceeding 4 ml per minute through a separate infusion line. Recommended dosing adjustments of $\pm$5 IU/kg should be based on trough FXIII activity levels of <5% or >20% as per package insert and the patient's clinical condition. Dosing may need to be adjusted following a bleeding event. Corifact™ is supplied as a single-use vial containing 1000-1600 IU of FXIII as a lyophilized concentrate. Each vial must be reconstituted and the actual FXIII potency (IU) for each lot is printed on the vial label and carton. According to the requester, there is no HCPCS code that describes this product.

CMS HCPCS Workgroup Preliminary Decision:

Establish Jxxx INJECTION, FACTOR XIII (ANTIHEMOPHILIC FACTOR, HUMAN), 1 I.U.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item, however; the applicant submitted written comments in agreement with the coding action and code text.

HCPCS Public Meeting Agenda Item #10
05/17/2011

Attachment# **11.021**

Topic/Issue:

Request to establish a code for cross-linked hyaluronate hydrogel, trade name: Gel-One®. Applicant's suggested language: "Hyaluronan or derivative, Gel-One, for intra-articular injection, one-dose".

Background/Discussion:

According to the requester, Gel-One is a sterile, transparent and viscoelastic gel composed of 30 mg of cross-linked hyaluronate hydrogel, a derivative of sodium hyaluronate. It is indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to non-pharmacologic therapy, non-steroidal anti-inflammatory drugs (NSAIDs) or analgesics. In knees with osteoarthritis, the joint fluid can break down and not provide the cushioning required by the knee joint. Hydrogel supplements the knee joint with viscoelastic fluid to relieve pain and improve the knee joint's natural shock-absorbing abilities. Hydrogel is physician-administered, and is injected directly into the cavity of the knee joint. It is delivered via a single-use, pre-filled disposable syringe containing three mL (30 mg) of Hydrogel. According to the requester, there are currently six hyaluronan products indicated to treat pain due to OA in the knee described by five existing HCPCS codes. However, none of these codes adequately describe Gel-One. A new code was established to facilitate accurate coding of the single dose hyaluronan product Synvisc-One, but that code does not adequately describe Hydrogel because it has a different chemical composition than Synvisc-One. In addition, the difference in total milligrams between the two products prohibits sharing a code.

CMS HCPCS Workgroup Preliminary Decision:

Establish Jxxxx HYALURONAN OR DERIVATIVE, GEL-ONE, FOR INTRA-ARTICULAR INJECTION, PER DOSE

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker thanked CMS for its preliminary decision and supported CMS' recommendation to create a new code for Gel-One.

HCPCS Public Meeting Agenda Item #11
05/17/2011

Attachment# **11.033**

Topic/Issue:

Request to establish a single new HCPCS code to identify Denosumab marketed under trade names: Prolia® and XGEVA™. Applicant's suggested language: Injection, Denosumab, 1 mg.

Background/Discussion:

According to the requester, Denosumab is a fully human antibody to the Receptor Activator of Nuclear factor-kB ligand (RANKL) that blocks it's binding to, inhibiting the development and activity of osteoclasts, decreasing bone resorption and increasing bone density. Prolia® is the trade name for the treatment of postmenopausal women with osteoporosis at high risk for fracture. The recommended dose is 60 mg once every six months administered as a subcutaneous injection. XGEVA™ is the trade name for prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors. The recommended dose is 120 mg every four weeks administered as a subcutaneous injection. According to the applicant, Denosumab is supplied in single -use prefilled syringes; single-use vials containing 60 mg of deliverable denosumab; and in single-use vials containing 120 mg of deliverable denosumab. Denosumab is billed using Not Otherwise Classified code J3590 on Medicare claims and for non-Medicare payers using HCPCS code C9272 (Injection, denosumab, 1 mg) on Medicare hospital outpatient claims. There is not an existing HCPCS code that identifies Denosumab or RANK ligand inhibitors.

CMS HCPCS Workgroup Preliminary Decision:

Establish Jxxxx INJECTION, DENOSUMAB, 1 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item; however, the applicant submitted written comments in agreement with the coding action and code text.

HCPCS Public Meeting Agenda Item #12
05/17/2011

Attachment# **11.074**

Topic/Issue:

Request to establish a code for alglucosidase alfa, trade name: Lumizyme®. Applicant's suggested language: "Alglucosidase alfa (Lumizyme), per 10 mg".

Background/Discussion:

According to the requester, Lumizyme is a purified form of the human enzyme acid alpha-glucosidase (GAA). It provides an exogenous source of GAA that increases the enzymatic activity in cleaving glycogen. Lumizyme is approved for use in patients 8 years of age and older with late (non-infantile) onset of Pompe disease that does not have evidence of cardiac hypertrophy. Pompe disease is a rare, inherited disorder caused by the deficiency of the human enzyme, GAA. The recommended dosage regimen of Lumizyme is 20 mg/kg body weight administered every 2 weeks as an intravenous infusion. Lumizyme is supplied in 20 mL vials containing 50 mg lyophilized cake or powder. According to the requester, the FDA considers Lumizyme a different product from Myozyme because of (1) a difference in the carbohydrate structures of the molecules; (2) different manufacturing processes; and (3) different indications for use. Also according to the requester, Lumizyme is a "single source drug" and as such, a separate price under Medicare's ASP payment program is warranted.

CMS HCPCS Workgroup Preliminary Decision:

1) Establish Jxxxx INJECTION, ALGLUCOSIDASE ALFA, (LUMIZYME), 10 MG
2) Revise code J0220 which currently reads INJECTION, ALGLUCOSIDASE ALFA, 10 MG to instead read INJECTION, ALGLUCOSIDASE ALFA, 10 MG, NOT OTHERWISE SPECIFIED

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker supported the workgroup's preliminary decision to create a code for alglucosidase alfa, Lumizyme.

HCPCS Public Meeting Agenda Item #13
05/17/2011

Attachment# **11.026**

Topic/Issue:

Request to establish a code for Ipilimumab, trade name: YERVOY™. Applicant's suggested language: "Injection, ipilimumab, 1 mg".

Background/Discussion:

According to the requester, YERVOY™ is a recombinant, human monoclonal antibody that binds to the Cytotoxic T-lymphocyte antigen-4 (CTLA-4) and blocks the interaction of CTLA-4 with its ligands. This action augments T-cell activation and proliferation and as such, indirectly enhances the T-cell mediated anti-tumor immune response. YERVOY is indicated for the treatment of unresectable or metastatic melanoma. It is supplied as 50-mg or 200-mg single-use vials each containing 10 mL or 40 mL, of a 5-mg/mL, sterile, isotonic solution for intravenous administration. The recommended induction regimen of YERVOY™ (ipilimumab) is 3 mg/kg administered every 3 weeks for a total of four doses. YERVOY is delivered via IV infusion over 90 minutes. It should not be administered as IV push or bolus injection. Ipilimumab injection can be used for IV administration without dilution or may be diluted with sterile sodium chloride 9 mg/mL (0.9% solution) or 5% dextrose injection solution to a concentration no less than 1 mg/mL. According to the requester, YERVOY is a novel and unique biologic and no other products are identified by this trade name or are marketed under the same active ingredient category/generic name.

CMS HCPCS Workgroup Preliminary Decision:

Establish Jxxxx INJECTION, IPILIMUMAB, 1 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #14
05/17/2011

Attachment# **11.002**

Topic/Issue:

Request to establish a new, product-specific HCPCS code within the J9000 range (for chemotherapy agents) for Dacogen® (decitabine) for Injection. This product is currently coded at J0894 "INJECTION, DECITABINE, 1 MG".

Background/Discussion:

According to the Requester, DACOGEN® (Decitabine) for Injection is for the treatment of adult patients with myelodysplastic syndrome (MDS). The first treatment cycle and recommended DACOGEN® dose is 15 mg/m2 administered by continuous intravenous infusion over 3 hours, repeated every 8 hours for 3 days. For subsequent treatment cycles - repeat above cycle every 6 weeks. It is recommended that patients be treated for a minimum of 4 cycles; a complete or partial response may take longer than 4 cycles. Treatment may be continued as long as the patient continues to benefit. DACOGEN® is supplied as a sterile lyophilized powder, in a single-dose vial, packaged in cartons of 1 vial. Each vial contains 50 mg of decitabine. The requester expressed concern that unless Dacogen is assigned to a code in the J9000 series, Medicare will stop paying for it. The requester also believes that Dacogen is a single-source drug and meets the criteria for separate Medicare payment under Section 1847A of the Act, and therefore requests that Dacogen be uniquely coded.

CMS HCPCS Workgroup Preliminary Decision:

Existing code J0894 INJECTION, DECITABINE, 1 MG adequately describes the product that is the subject of this request. This code category does not belong elsewhere in the HCPCS code set.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #15
05/17/2011

Attachment# **11.003**

Topic/Issue:

Request to establish a code in the J9000 series for eribulin mesylate for injection, trade name: HALAVEN™. Applicant's suggested language: "Eribulin mesylate for injection - 1 mg".

Background/Discussion:

According to the requester, eribulin mesylate (HALAVEN) is a non-taxane microtubule inhibitor that belongs to the halichondrin class of antineoplastic agents. It is indicated for the treatment of locally advanced or metastatic breast cancer in patients who have previously received at least two chemotherapeutic regimens, including an anthracycline and a taxane. Eribulin inhibits the growth phase of microtubule dynamics without affecting the shortening phase and sequesters tubulin into nonproductive aggregates. The recommended dose of eribulin is 1.4 mg/m^2 administered intravenously over 2 to 5 minutes on Days 1 and 8 of a 21-day cycle. Premedication with steroids and/or antihistamines to prevent hypersensitivity reactions is not required with the use of eribulin. Eribulin is supplied as 1.0 mg eribulin mesylate in a single-use vial individually packaged in a carton. According to the requester, it is anticipated that eribulin will be proven to be a new alternative therapy for metastatic breast cancer and as such, a new and unique code in the J9000 series is needed in order to ensure access to this product.

CMS HCPCS Workgroup Preliminary Decision:

Establish Jxxxx INJECTION, ERIBULIN MESYLATE, 0.1 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #16
05/17/2011

Attachment# **11.013**

Topic/Issue:

Request to establish a code for Cabazitaxel injection, trade name: Jevtana®. Applicant's suggested language: Jxxxx "Cabazitaxel for injection, 1 mg".

Background/Discussion:

According to the requester, Jevtana® is a microtubule inhibitor indicated for use in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen. It is an antineoplastic that binds to tubulin and promotes its assembly into microtubules while simultaneously inhibiting disassembly. This leads to stabilization of microtubules, which results in the inhibition of mitotic and interphase cellular functions. Jevtana® requires a two-step dilution prior to administration and the concentration of the Jevtana® infusion solution should be between 0.10mg/ml and 0.26 mg/ml. If a dose greater than 65 mg is required, use a larger volume of the infusion vehicle so that a concentration of 0.26 mg/ml is not exceeded. The recommended adult dose is 25 mg/m^2 administered every 3 weeks as a 1-hour intravenous infusion in combination with oral prednisone 10 mg administered daily throughout Jevtana® treatment. A premedication regimen is administered at least 30 minutes before each dose of Jevtana® to reduce the risk and/or severity of hypersensitivity. The premedication regimen is as follows: antihistamine (dexchloropheniramine 5 mg, diphenhydramine 25 mg or equivalent), corticosteroid (dexamethasone 8 mg or equivalent), and H2 antagonist (ranitidine or equivalent). Jevtana® is supplied as a kit containing one-single use vial 60 mg/1.5mL and one 5.7 mL vial of diluent. Both items are in a blister pack in one carton. According to the requester, there are no existing codes to describe Jevtana and a new, unique HCPCS code will facilitate access to this product and allow payer systems to capture important product-specific data.

CMS HCPCS Workgroup Preliminary Decision:

Establish Jxxxx INJECTION, CABAZITAXEL, 1 MG

Summary of Primary Speaker Comments at the Public Meeting:

The applicant offered a brief comment at the public meeting agreeing with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #17
05/17/2011

Attachment# **11.072**

Topic/Issue:

Request to establish a code for Sipuleucel-T, trade name: PROVENGE®. Applicant's suggested language: "Sipuleucel-T, 250 mL".

Background/Discussion:

According to the Requester, PROVENGE® (sipuleucel-T) is classified as an autologous cellular immunotherapy indicated for the treatment of a symptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. PROVENGE® consists of autologous peripheral blood mononuclear cells, including antigen presenting cells (APCs) that have been activated during a defined culture period with a recombinant human protein, PAP-GM-CSF, consisting of prostatic acid phosphatase (PAP), an antigen expressed in prostate cancer tissue, linked to granulocyte-macrophage colony-stimulating factor (GM-CSF), an immune cell activator. The patient's peripheral blood mononuclear cells are obtained via a standard leukapheresis procedure approximately 3 days prior to the infusion date. The active components of PROVENGE® are autologous APCs and PAP-GM-CSF. During culture, the recombinant antigen can bind to and be processed by APCs into smaller protein fragments. While the precise mechanism of action is unknown, the recombinant antigen is designed to target APCs and may help direct the immune response to PAP. Minimal residual levels of the intact PAP-GM-CSF are detectable in the final PROVENGE® product. The cellular composition of PROVENGE® is dependent on the composition of cells obtained from the patient's leukapheresis. In addition to APCs, the final product contains T cells, B cells, natural killer (NK) cells, and other cells. The number of cells present and the cellular composition of each PROVENGE® dose will vary. The course of therapy for PROVENGE® (sipuleucel-T) is 3 doses, 250 mL each, given at approximately 2-week intervals by intravenous infusion over approximately 60 minutes. PROVENGE® (sipuleucel-T) is supplied in a sealed, patient-specific infusion bag containing a minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF suspended in 250 mL of Lactated Ringer's Injection, USP.

CMS HCPCS Workgroup Preliminary Decision:

Newly established code Q2043 SIPULEUCEL-T, MINIMUM OF 50 MILLION AUTOLOGOUS CD54+ CELLS ACTIVATED WITH PAP-GM-CSF, INCLUDING LEUKAPHERESIS AND ALL OTHER PREPARATORY PROCEDURES, PER INFUSION effective 7/1/2011 adequately describes Provenge.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision that the newly established Q code adequately describes PROVENGE®. The speaker urged the Workgroup to discontinue the "Q" code and "create a permanent J-code for PROVENGE® effective 1/1/12, consistent with prior coding action for coding certain drugs. The speaker suggested that CMS consider Provenge to be a drug and reimburse for it as such. The speaker also suggested that the code text describe the end product only, and that the autologous cell collection and leukapheresis not be mentioned in the code text. The suggested language is "Sipuleucel-T, 250 mL."

HCPCS Public Meeting Agenda Item #18
05/17/2011

Attachment# **11.005**

Topic/Issue:

Request to establish a code for everolimus, trade name: Zortress®.

Background/Discussion:

According to the requester, Zortress® is a macrolide immunosuppressant indicated for the prophylaxis of organ rejection in adult kidney transplant patients at low to moderate immunologic risk receiving a kidney transplant. It allows for use of reduced doses of nephrotoxic calcineurin inhibitors without loss of immunosuppressive activity while maintaining renal function. Zortress® is to be used in combination with basiliximab induction and concurrently with reduced doses of cyclosporine and corticosteroids. The recommended initial dosage of 0.75 mg is given twice daily in combination with reduced dose CsA, administered as soon as possible after transplantation. Patients may require dose adjustments. Dose adjustments can be made at 4-5 day intervals. Zortress® is supplied as tablets for oral administration containing 0.25 mg, 0.5 mg and 0.75 mg of everolimus. Each strength is available in boxes of 60 (6 blister strips of 10 tablets each). According to the requester, there are no known product-specific codes for this "single source drug".

CMS HCPCS Workgroup Preliminary Decision:

Establish Jxxxx EVEROLIMUS, ORAL, 0.25 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item; however, a manufacturer's representative offered a comment at the public meeting agreeing with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #19
05/17/2011

Attachment# **11.121**

Topic/Issue:

Request to establish a code for hydroxyprogesterone caproate injection for intramuscular use, trade name: Makena™. Applicant's suggested language: "Hydroxyprogesterone caproate injection, for intramuscular use, 250 mg (Makena)".

Background/Discussion:

According to the requester, Makena™ (Hydroxyprogesterone Caproate Injection) is a synthetic progestin and is the first and only FDA approved progestin indicated for the prevention of preterm birth in women with a singleton pregnancy that have a history of singleton spontaneous preterm birth. Preterm birth is defined as delivery before 37 weeks gestation. The mechanism by which Makena prevents preterm birth is not known. Makena™ is administered intramuscularly at a dose of 250 mg (1 mL) once weekly. Treatment is begun between 16 weeks, 0 days and 20 weeks, 6 days of gestation and given weekly until week 37 of gestation or delivery, whichever occurs first. Makena™ is packaged in a 5mL multi-dose vial which contains 1250 mg hydroxprogesterone caproate (250 mg/mL); each multi-dose vial contains 5 doses. According to the applicant, a code is needed to describe Makena™, and use of a "not otherwise classified" code for Makena™ would result in manual claims processing causing delays in claims payment and errors in determining an accurate payment rate.

CMS HCPCS Workgroup Preliminary Decision:

1) Newly established Q2042 INJECTION, HYDROXYPROGESERONE CAPROATE, 1 MG adequately describes Makena. effective 7/1/2011
2) Discontinue Q2042 INJECTION, HYDROXYPROGESTERONE CAPROATE, 1 MG effective 12/31/2011
3) Establish Jxxxx INJECTION, HYDROXPROGESTERONE CAPROATE, 1 MG effective 1/1/2012

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #20
05/17/2011

Attachment# **11.012**

Topic/Issue:

Request to establish a code for incobotulinumtoxinA, trade name: Xeomin®. Applicant's suggested language: "Injection, incobotulinumtoxinA, per unit".

Background/Discussion:

According to the requester, Xeomin® is indicated for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia; and for treatment of blepharospasm in adults. The optimum dose and number of injection sites in each treated muscle should be individualized and is based on the number and location of the muscle(s) to be treated, degree of over-activity muscle mass, body weight and response to prior botulinum toxin injections. Doses should be titrated. For cervical dystonia, the total dose is from 120 to 300 U per treatment. The recommended initial dose is 120 units. For benign essential blepharospasm, no more than 50U per eye, per treatment. The initial dose in both eyes should not exceed 70 units. Frequency of Xeomin repeat treatments should be determined by clinical response, but should generally be no more frequent than every 12 weeks. Xeomin is supplied in vials containing $50LD_{50}$ Units and $100LD_{50}$ Units, lyophilized powder for injection. According to the requester, there is no existing HCPCS code to describe incobotulinumtoxinA, thus a unique HCPCS code is warranted in order to identify this unique biologic.

CMS HCPCS Workgroup Preliminary Decision:

1) Use newly established code Q2040 INJECTION, INCOBOTULINUMTOXIN A, 1 UNIT, effective 4/1/2011. Adequately describes Xeomin.
2) Discontinue Q2040 effective 12/31/11
3) Establish code Jxxxx INJECTION, INCOBOTULINUMTOXIN A, 1 UNIT (eff. 1/1/12)

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #21
05/17/2011

Attachment# **11.030**

Topic/Issue:

Request to establish a code for Pegloticase, trade name: KRYSTEXXA□□ pplicant's requested language: "Injection, Pegloticase, 8 mg."

Background/Discussion:

According to the requester, KRYSTEXXA™ (Pegloticase), a PEGylated uric acid specific enzyme, is the first and only therapy indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. KRYSTEXXA™ achieves its therapeutic effect by catalyzing the oxidation of uric acid to allantoin, thereby lowering serum uric acid. Allantoin is an inert and water purine metabolite, readily eliminated, primarily by renal excretion. The recommended dose and regimen of KRYSTEXXA™ for adult patients is 8 mg (uricase protein) given as an intravenous infusion every two weeks. The optimal treatment duration has not been established. The KRYSTEXXA™admixture should only be administered by intravenous infusion over no less than 120 minutes via gravity feed, syringe-type pump, or infusion pump. It should not be administered as an I.V. push or bolus. KRYSTEXXA™ is supplied as a solution in phosphate buffered saline intended for intravenous infusion after dilution. KRYSTEXXA™ is supplied in a single-use 2 mL glass vial to deliver KRYSTEXXA™ as 8 mg of uricase protein in 1 mL volume. According to the requester, there are no therapeutically equivalent products with the same active ingredient and administration form, and there are no HCPCS codes that describe Krystexxa.

CMS HCPCS Workgroup Preliminary Decision:

Establish Jxxxx INJECTION, PEGLOTICASE, 1 MG. Until the J code is established, new code C9281"INJECTION, PEGLOTICASE, 1 MG" is available for assignment by all insurers if they deem appropriate.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item, however; the applicant submitted written comments in agreement with CMS' preliminary decision.

HCPCS Public Meeting Agenda Item #22
05/17/2011

Attachment# **11.034**

Topic/Issue:

Request to establish two HCPCS codes for Ondansetron, trade name: Zuplenz. Applicant's suggested language: Sxxxx Ondansetron oral soluble film, 4 mg; and Qxxxx Odansetron oral soluble film, 8 mg, FDA approved prescription anti-emetic, for use as a complete substitute for an I.V. anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Background/Discussion:

According to the requester, Zuplenz represents the first non-OTC pharmaceutical oral soluble film (OSF) approved for marketing by the FDA. Zuplenz is an antiemetic, indicated for postoperative, highly and moderately emetogenic cancer chemotherapy-induced, and radiotherapy-induced nausea and vomiting. Zuplenz is supplied as a thin film strip in an individual foil-sealed pouch and is available in 4 mg and 8 mg oral soluble film strengths. Zuplenz is administered by placing the film strip on top of the tongue, where it dissolves in seconds and can be swallowed without water. According to the applicant, the requested new codes are needed to report a new and distinct oral dosage form, oral soluble film.

CMS HCPCS Workgroup Preliminary Decision:

1) Discontinue code Q0179 ONDANSETRON HYDROCHLORIDE 8 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
2) Establish Qxxxx ONDANSETRON 1 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
The new code may be assigned to any oral dose form available. The number of mg administered can be reported in the "units" column on the claim. A national program operating need was not identified by any insurance sector to distinguish, via HCPCS coding, different oral dosage forms.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #23
05/17/2011

Attachment# **11.041**

Topic/Issue:

Request to establish a code for Lacosamide, trade name: VIMPAT®. Applicant's suggested language: "Injection, lacosamide, 1 mg".

Background/Discussion:

According to the requester, VIMPAT® is an intravenous antiepileptic drug (AED) indicated as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older when oral administration is temporarily not feasible. The precise mechanism by which VIMPAT® injection exerts its antiepileptic effects is unknown. In vitro electrophysiological studies have shown that lacosamide selectively enhances slow inactivation of voltage-gated sodium channels, resulting in stabilization of hyper-excitable neuronal membranes and inhibition of repetitive neuronal firing. It is administered by intravenous infusion as follows: Partial onset seizures: 50 mg twice daily (100 mg/day). Additional dosing increments (100 mg/ day given as two divided doses every week) may be given up to a maximum recommended daily dose of 200 to 400 mg/day. VIMPAT® may be given without further dilution or mixed in compatible diluent and should be administered intravenously over a period of 30 to 60 minutes. Switching from oral to intravenous dosing: the initial total daily intravenous dosage of VIMPAT® injection should be equivalent to the total daily dosage and frequency of oral VIMPAT® and should be infused intravenously over a period of 30 to 60 minutes. VIMPAT Injection (200 mg/20 mL) is supplied in single-use 20 mL vials, available in cartons of 10 vials. According to the requester, VIMPAT is a unique, single-source drug, and there is no existing HCPCS code to describe it. Existing code C9254 "INJECTION, LACOSAMIDE, 1 MG" does not adequately describe this product because: 1) C codes are not sufficient for non-Medicare payers because many state Medicaid programs do not use C codes; and 2) this decision is inconsistent with CMS' coding decisions for other products in the anti-epileptic drug (AED) class.

CMS HCPCS Workgroup Preliminary Decision:

Existing code C9254 INJECTION, LACOSAMIDE, 1MG adequately describes this product. Insurers that choose not to assign HCPCS "C" codes may use NDC codes to describe this item.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item. The applicant submitted written comments in appreciation of CMS' transparent process and the opportunity to speak and stated that

UCB would continue to monitor patient access to this product, and based on their findings, they may reapply at a later date.

HCPCS Public Meeting Agenda Item #24
05/17/2011

Attachment# **11.050**

Topic/Issue:

Request to establish a code for Ceftaroline Fosamil for IV administration, trade name: Teflaro®. Applicant's suggested language: "Injection, ceftaroline fosamil, 200 mg".

Background/Discussion:

According to the requester, Teflaro is indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI) caused or strongly suspected to be caused by certain susceptible bacteria. Teflaro has bactericidal activity against gram positive and gram negative bacteria, which are associated with skin and respiratory infections. This action results from inhibition of cell wall synthesis by high affinity binding to penicillin-binding proteins (PBPs). Teflaro is administered as a pro-drug that is rapidly converted in plasma to the active metabolite ceftaroline. The recommended clinical dose of Teflaro is 600 mg administered via a one-hour intravenous infusion by a health care professional every 12 hours for a treatment duration of 5-14 days depending on indication, severity, infection site, and patient's clinical and bacteriological progress. Dosage adjustment is required for patients with renal impairment. Teflaro is supplied in single-use vials containing either 600 mg or 400 mg of ceftaroline fosamil powder. According to the requester, there are no other cephalosporins that are active against MRSA, and Teflaro is a single-source drug that meets the criteria under section 1847A of the Act for separate pricing under Medicare's ASP pricing program.

CMS HCPCS Workgroup Preliminary Decision:

Establish Jxxxx INJECTION, CEFTAROLINE FOSAMIL, 10 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item, however; a written comment was submitted encouraging CMS to finalize its preliminary coding decision.

HCPCS Public Meeting Agenda Item #25
05/17/2011

Attachment# **11.123**

Topic/Issue:

Request to establish a code for Minocycline Hydrochloride, trade name: MINOCIN.

Background/Discussion:

According to the requester, MINOCIN® is an antibiotic indicated for the treatment of infections due to susceptible isolates of the designated bacteria and infections caused by Gram-negative and Gram-positive bacteria when bacteriologic testing indicates appropriate susceptibility to the drug. Minocycline is an alternative drug of several infections when penicillin is contraindicated. It may also be useful as an adjunct to amebicides and as an adjunctive therapy in severe acne. MINOCIN® is a member of the tetracycline class of antibiotics. Tetracycline exerts their antimicrobial effect by the inhibition of protein synthesis. MINOCIN® is given intravenously. Usual pediatric dose is 4 mg/kg, then 2 mg/kg every 12 hours not to exceed the usual adult dose. Usual adult dose is 200 mg, then 100 mg every 12 hours and should not exceed 400 mg in 24 hours. MINOCIN® is supplied as 100 mg vials of cryodesiccated powder. According to the requester, there is no existing HCPCS code to describe this product.

CMS HCPCS Workgroup Preliminary Decision:

Establish Jxxxx INJECTION, MINOCYCLINE HYDROCHLORIDE, 1 MG

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #26
05/17/2011

Attachment# **11.052**

Topic/Issue:

Request to establish a code for Mannitol inhalation powder, trade name: Aridol. Applicant's suggested language: "Mannitol inhalation powder administered through an inhaler, per 635 mg".

Background/Discussion:

According to the requester, Aridol is indicated for use as a challenge test in the assessment of bronchial hyper-responsiveness in individuals at least six years of age who do not have clinically apparent asthma. Aridol is a dry powder form of mannitol administered through an inhaler. Aridol works by causing bronchial hyper-responsiveness in patients with a probable diagnosis of asthma. To cause this response, Aridol is administered through a series of graduated challenge tests involving sequential inhalation of increasingly greater doses of the drug. Dosage begins at 5 mg and reaches up to 160 mg per administration. The test is complete upon either eliciting a positive response, or inhalation of all 9 doses without any response. Aridol is sold in a package containing one single patient use inhaler and three foil blister packs holding 19 Aridol capsules that make up the 9 dosages necessary to do a complete bronchial challenge test. Dose 1 is 1 clear, empty capsule. Dose 2 is one 5 mg capsule. Dose 3 is one 10 mg capsule. Dose 4 is one 20 mg capsule. Dose 5 is one 40 mg capsule. Dose 6 is two 40 mg capsules. Doses 7, 8 and 9 are each four 40 mg capsules. According to the requester, mannitol powder is different from mannitol IV (currently coded). Aridol is furnished usually in physician's offices and outpatient settings. Aridol is a "single-source" drug. And for these reasons, a new HCPCS code is warranted.

CMS HCPCS Workgroup Preliminary Decision:

This is a supply to a challenge test. Since the single-use inhaler used during the test does not qualify the inhaler as DME, the mannitol is not a DME supply. Existing CPT code 99070 SUPPLIES AND MATERIALS (EXCEPT SPECTACLES), PROVIDED BY THE PHYSICIAN OVER AND ABOVE THOSE USUALLY INCLUDED WITH THE OFFICE VISIT OR OTHER SERVICES RENDERED (LIST DRUGS, TRAYS, SUPPLIES, OR MATERIALS PROVIDED) is available for assignment by insurers if they deem appropriate. Medicare, Medicaid and the Private Insurance sector did not identify a national program operating need to establish a HCPCS Level II code for this supply to a challenge test.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the workgroup's preliminary decision and asked for reconsideration. According to the speaker, the benefit category for Aridol is a drug incident to a physician's service (and not a drug incident to DME); secondly, Aridol is a single source drug and is reimbursed at an average sales price plus 6 percent so there is a programmic need to determine on a claims form when the product is used. Thirdly, the use of a bundled code for extraordinary supplies without separate payment is inappropriate because Aridol is not otherwise taken into account in the weighting of the CPT codes used to describe the related procedure (i.e., bronchial challenge testing).

HCPCS Public Meeting Agenda Item #27
05/17/2011

Attachment# **11.058**

Topic/Issue:

Request to establish a code for a lidocaine 70 mg/tetracaine 70 mg topical patch, trade name; SYNERA®.

Background/Discussion:

According to the requester, SYNERA® is a single-use topical anesthetic patch with a novel, controlled heat-assisted drug delivery device (CHADD) that enhances the delivery of the local anesthetic, a eutectic mixture of equal parts lidocaine and tetracaine. The CHADD technology allows SYNERA® to provide faster onset and greater depth and duration of analgesia than other topically-administered products. The SYNERA® patch is applied to intact skin to provide local dermal analgesia prior to painful procedures such as needle punctures and superficial dermatological procedures. SYNERA® is indicated for use in adults and children 3 years of age and older. It is applied 20 - 30 minutes prior to venipuncture or intravenous cannulation. For superficial dermatological procedures, SYNERA® is applied for 30 minutes prior to the procedure. SYNERA® is supplied as a package containing one SYNERA® patch and as a box of ten individually packaged patches. Each patch contains a eutectic mixture of lidocaine 70 mg and tetracaine 70 mg. According to the requester, there are no existing HCPCS codes to describe this product.

CMS HCPCS Workgroup Preliminary Decision:

A national program operating need to establish a code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, and a determination regarding whether this item is separately billable, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact Medicare contractor.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #28
05/17/2011

Attachment# **11.066**

Topic/Issue:

Request to establish a code for testosterone pellets for subcutaneous implantation, trade name: Testopel® Pellets. Applicant's suggested language: Testopel Testosterone Pellet, 75 mg each.

Background/Discussion:

According to the requester, Testopel® is the only FDA-approved testosterone replacement therapy that can normalize testosterone for 3-6 months in a single dose. 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, Testopel pellets are currently identified on claims using existing code J3490 UNCLASSIFIED DRUGS or S0189 TESTOSTERONE PELLET, 75 MG. The requester considers these to be non-otherwise-classified codes since the language does not specify Testopel® for male hormone replacement by brandname. As such, these codes do not enable utilization tracking, and results in underpayment. A specific "J" code is needed for Medicare reimbursement."

CMS HCPCS Workgroup Preliminary Decision:

A national program operating need to establish a new code for this product was not identified by Medicare, Medicaid or the Private Insurance Sector. Code S0189 adequately describes Testopel and is available for assignment by insurers if they deem appropriate. 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, contact the Medicare contractor.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #29
05/17/2011

Attachment# **11.073**

Topic/Issue:

Request to establish a code for acetaminophen injection for IV use, trade name: OFIRMEV™. Applicant's suggested language: "Acetaminophen injection, 10 mg/mL, 1000 mg".

Background/Discussion:

According to the Requester, OFIRMEV™ is a non-opioid, non-steroidal anti-inflammatory drug (NSAID). It is the first and only IV formulation of acetaminophen available in the U.S. OFIRMEV™ produces a rapid onset of action within an hour and the duration of effect is usually 4 to 6 hours. It is indicated for the management of mild to moderate pain; management of moderate to severe pain with adjunctive opoid analgesics; and for fever reduction in adults and children 2 years or older. OFIRMEV™ may be given as a single or repeated dose and be administered only as a 15-minute IV infusion. For adults and adolescents weighing at least 50kg, the recommended dose is 650 to 1,000 mg up to a maximum dose of 4000 mg per 24 hours minimum dose interval of 4 hours. For adults and adolescents weighing under 50 kg, and for all children, the recommended dose is 12.5 mg/kg every 4 hours or 15 mg/kg every 6 hours to a max of 75 mg/kg in 24 hours. OFIRMEV™ is supplied as a single-use drug in a 100 mL vial containing 1000 mg acetaminophen (10 mg/mL). According to the requester, as a unique drug OFIRMEV™ is not appropriately described by an existing HCPCS codes.

CMS HCPCS Workgroup Preliminary Decision:

Establish Jxxxx INJECTION, ACETAMINOPHEN, 10 MG

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker supported CMS' preliminary decision to establish a code for OFIRMEV™.

HCPCS Public Meeting Agenda Item #30
05/17/2011

Attachment# **11.119**

Topic/Issue:

Request to establish 2 new HCPCS codes for Baclofen injection, trade name: Gablofen®. Applicant's suggested language: "Gablofen (Baclofen, injection), 10 mg"; and "Gablofen (Baclofen, injection), 50 mcg for intrathecal trial".

Background/Discussion:

According to the requester, Gablofen® is a gamma-aminobutyric acid (GABA) ergic agonist indicated for use in the management of severe spasticity of cerebral or spinal origin in adult and pediatric patient's ages 4 years and older. It is intended for use by intrathecal route in single bolus test doses and for chronic use in the Medtronic SynchroMed II Programmable pump or other pumps labeled for intrathecal administration of Gablofen®. Prior to implantation of a device for chronic intrathecal infusion of Gablofen®, patients must show a response to Gablofen® in a screening trial. Typically, patients need to go to the physician's office every 90 days to have the implantable pump refilled with Gablofen®. Gablofen® is supplied as: 1 mL syringe (50 mcg per 1 mL), 20 ml vial (10 mg per 20 mL), and 20 mL vial (40 mg per 20 mL). According to the requester existing codes J0475 "INJECTION, BACLOFEN, 10 MG" and J0476 "INJECTION, BACLOFEN, 50 MCG FOR INTRATHECAL TRIAL" are used to bill Lioresal® and Lioresal® intrathecal refill kit. Lioresal is similar to Gablofen; has the same indications for use and mechanism of action; is supplied in the same concentrations; and Gablofen is listed as a generic in the FDA Orange Book.

CMS HCPCS Workgroup Preliminary Decision:

Existing code J0475 INJECTION, BACLOFEN, 10 MG or J0476 INJECTION, BACLOFEN, 50 MCG FOR INTRATHECAL TRIAL based on size and use adequately describes the product that is the subject of this request.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant submitted written comments of agreement with CMS' preliminary decision.

PAYMENT FOR PART B DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Background

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

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

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

Drugs Paid on a Cost or Prospective Payment Basis

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

Part B Drug Payment Methodology

Historical Payment Methodology

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

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

Current Methodology

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

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

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

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

Exceptions to ASP pricing methodology

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

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

Payment for Radiopharmaceuticals

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

Dispensing/Supplying/Furnishing Fees

Dispensing Fees

During calendar year (CY) 2010, Medicare paid 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.

During CY 2010, Medicare also paid 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.

During CY 2010, the pharmacy also received 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.

During CY 2010, Medicare paid 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, during CY 2010, Medicare paid a supplying fee of $16.00 to a pharmacy for each subsequent prescription, after the first one, of immunosuppressive, oral anti-cancer, or oral anti-emetic drugs supplied to a beneficiary during a 30-day period. Medicare pays the supplying fee for each prescription, including prescriptions for different strengths of the same drug supplied on the same day (for example, prescriptions for 100mg tablets and 5 mg tablets).

Furnishing Fees

In 2005, Medicare began a furnishing fee per unit of clotting factor to entities that furnish blood clotting factor unless the costs of furnishing the

blood clotting factor are paid through another payment system. In each year, the prior year's fee is increased by the percentage increase in the consumer price index for medical care for the 12-month period ending June of the previous year. For CY 2010, this fee was $0.17 per unit.

Part B versus Part D

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

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

http://www.cms.hhs.gov/PrescriptionDrugCovContra

http://www.cms.hhs.gov/Pharmacy

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