Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Drugs, Biologicals, and Radiopharmaceuticals
Wednesday, May 21, 2014

Introduction and Overview

Approximately 75 people attended. The agenda included 21 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.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.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.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.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.gov/medhcpcsgeninfo/downloads/decisiontree.pdf.

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Drugs, Biologicals and Radiopharmaceuticals
Wednesday, May 21, 2014 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# 14.044
Request to revise the descriptor of Level II HCPCS code S0189 to either include the brand name "Testopel"; or to specify FDA approved, non-compounded final product.

Primary Speaker: Timothy E. Hermes of Auxilium Pharmaceuticals

AGENDA ITEM #2
Attachment# 14.015
Request to establish a new Level II HCPCS code to identify testosterone replacement therapy (testosterone undecanoate), trade name: AVEED.

No Primary Speaker

AGENDA ITEM #3
Attachment# 14.002
Request to revise the text of existing code J7302 which currently reads: "Levonorgestrel-releasing intrauterine contraceptive system, 52mg" to instead read: "Levonorgestrel-releasing intrauterine contraceptive system (Mirena), 52mg".

Primary Speaker: Dr. Edio Zampaglione of Bayer HealthCare

AGENDA ITEM #4
Attachment# 14.047
Request to establish a new Level II HCPCS code to identify injectable radiopharmaceutical Radium Ra 223 Dichloride, trade name: Xofigo. Applicants suggested language: Radium Ra 223 dichloride, therapeutic, per treatment dose.

Primary Speaker: William Sarraille of Sidley Austin, LLP

AGENDA ITEM #5
Attachment# 14.056
Request to modify the language of existing code J0135, which currently reads: "Injection, Adalimumab, 20mg"; to instead read: "Injection, Adalimumab, 20mg" (code may be used for Medicare when drug is administered under the direct supervision of a physician, not for use when drug is self-administered).

No Primary Speaker

AGENDA ITEM #6
Attachment# 14.045
Request to establish a new Level II HCPCS code to identify a sodium hyaluronate derivative, trade name: Monovisc™. Applicant's suggested language: JXXXX Hyaluronan or Derivative, Monovisc™, For Intra-Articular Injection, Per Dose.

Primary Speaker: Dr. Herbert S.B. Baraf of George Washington University

AGENDA ITEM #7
Attachment# 14.003
Request to establish a new Level II HCPCS code to identify a radioactive diagnostic agent for PET imaging, Florbetapen (18F), trade name: Neuraceq. Applicant's suggested language: AXXXX Injection, Florbetaben 18F, diagnostic, per study dose, up to 8.1 millicures.

Primary Speaker: Dr. Andrew Stephens of Piramal Imaging

AGENDA ITEM #8
Attachment# 14.048
Request to modify the dose descriptor of existing code J7335 which currently reads: "Capsaicin 8% Patch, Per 10 Square Centimeters" to instead read: "Capsaicin 8% Patch, Per Patch".

Primary Speaker: Steve Sandor of Acorda Therapeutics

AGENDA ITEM #9
Attachment# 14.033
Request to establish a new Level II HCPCS code to identify Coagulation Factor IX [Recombinant], trade name: Rixubis. Applicant's suggested language: JXXXX Factor IX (Antihemophilic Factor, Recombinant), Rixibus, Per I.U.

No Primary Speaker

AGENDA ITEM #10
Attachment# 14.055
Request to establish a new Level II HCPCS code to identify a typical antipsychotic, Loxapine, trade name: Adasuve. Applicant's suggested language: JXXXX Loxapine, Inhalation Powder, 10mg.

No Primary Speaker

AGENDA ITEM #11
Attachment# 14.051
Request to establish a unique Level II HCPCS code to identify solvent/detergent treated pooled human plasma, trade name: Octaplas®. Applicant's suggested language: Injection, pooled Plasma (Human), Solvent/detergent treated (Octoplas), 200mL. OR, if a new code is not established, the applicant requests a change in reimbursement level for existing code P9023.

Primary Speaker: Stuart Langbein of Hogan Lovells

AGENDA ITEM #12
Attachment# 14.036
Request to establish a new Level II HCPCS code to identify a monoclonal antibody, obinutuzumab, trade name: Gazyva. Applicant's suggested language: JXXXX Injection, Obinutuzumab, 100mg.

No Primary Speaker

AGENDA ITEM #13
Attachment# 14.034
Request to establish a new Level II HCPCS code to identify ferric carboxymaltose iron

replacement, trade name: Injectafer. Applicant's suggested language: JXXXX Injection, Ferric Carboxymaltose, 1mg.

No Primary Speaker

AGENDA ITEM #14
Attachment# 14.013
Request to establish a new Level II HCPCS code to identify Low Nitrogen 1% Polidocanol Injectable, Foam, trade name: Varithena. Applicant's suggested language:

JXXXX Low Nitrogen 1% Polidocanol Injectable foam; Sterile canister, 1ml.

Primary Speaker: Dr. Kathleen Gibson of Lake Washington Vascular

AGENDA ITEM #15
Attachment# 14.006
Request to establish a new Level II HCPCS code to identify a local anesthetic administered into a surgical site, (bupivacaine liposome injectable suspension), trade name: Exparel.

Primary Speaker: Dr. Erol Onel of Pacira Pharmaceuticals, Inc.

AGENDA ITEM #16
Attachment# 14.042
Request to establish a Level II HCPCS code to identify Kcentra, and to discontinue existing code C9132, (which describes Kcentra). Applicant's suggested language:

JXXXX Kcentra Prothrombin Complex Concentrate, Kcentra, Each Factor IX IU

Primary Speaker: Stuart Langbein of Hogan Lovells

AGENDA ITEM #17
Attachment# 14.049
Request to establish a new Level II HCPCS code to identify an optical imaging agent, hexaminolevulinate hydrochloride, trade name: Cysview. Applicant's suggested language: JXXXX Injection, Hexaminolevulinate Hydrochloride For Intravesical Instillation, 100mg.

Primary Speaker: Dr. Gary Steinberg of Urology University of Chicago Medical Center

AGENDA ITEM #18
Attachment# 14.004
Request to establish a new Level II HCPCS code to identify an enzyme replacement therapy for Mucopolysaccharidosis type IVA; elosulfase alfa, trade name: VIMIZIM. Applicant's suggested language: JXXXX Injection, Elosulfase Alfa For Intravenous Infusion, 1mg.

No Primary Speaker

AGENDA ITEM #19
Attachment# 14.001
Request to establish a new Level II HCPCS code to identify TRETTEN® Coagulatin Factor XIII (recombinant). Applicant's suggested language: JXXXX Injection Factor XIII (Tretten Coagulation Factor XIII A-Subunit (Recombinant)), Per IU.

No Primary Speaker

AGENDA ITEM #20
Attachment# 14.008
Request to establish a new Level II HCPCS code to identify Novoeight® Antihemophilic factor VIII (Recombinant). Applicant's suggested language: JXXXX Injection, factor VIII (Novoeight® Antihemophilic factor (Recombinant)), Per IU.

No Primary Speaker

AGENDA ITEM #21
Attachment# 14.007
Request to establish a new Level II HCPCS code to identify Flutemetamol F18 injection, trade name: Vizamy™. Applicant's suggested language: AXXXX Flutemetamol F18, Diagnostic, Per Study Dose, Up To 5 Millicuries.

Primary Speaker: Jane Majcher of GE Healthcare

HCPCS Public Meeting Agenda Item #1

May 21, 2014

Attachment# 14.044

Topic/Issue:

Request to revise the descriptor of Level II HCPCS code S0189 to either include the brand name "Testopel"; or to specify FDA approved, non-compounded final product.

Background/Discussion:

According to the requester, Testopel® is the only FDA approved testosterone pellet for replacement therapy, in conditions associated with a deficiency or absence of endogenous testosterone. Testopel® is implanted via subcutaneous injection performed by a physician, usually in the hip area, where it will dissolve over a timeframe of three to six months. Testopel is supplied as 75mg "pellets", one pellet per vial; in boxes of 10 vials. The requester comments that code revisions are needed in order to ensure that coders and payers can distinguish between the FDA approved final product, and a compounded testosterone pellet product produced in a compounding pharmacy.

Preliminary Decision:

Existing code S0189 "Testosterone Pellet, 75mg", adequately describes Testopel. The proposed revision does not improve the code descriptor. A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to revise the descriptor of HCPCS code S0189 or to establish an additional code to identify Testopel.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker commented that the preliminary decision fails to recognize the significant safety issues with compounded forms of testosterone pellets. There is a national program operating need for unique coding on the part of non- Medicare payers, specifically, Private Insurers need to differentiate. The speaker stated that revising the descriptor for S0189 would address concerns identified by the OIG in its examination of compounded drugs. The speaker recommended that CMS revise the descriptor of existing code S0189 by either including "Testopel" in the language of the descriptor, or revising the descriptor to clarify that the code is for a non-compounded, final product.

HCPCS Public Meeting Agenda Item #2

May 21, 2014

Attachment# 14.015

Topic/Issue:

Request to establish a new Level II HCPCS code to identify testosterone replacement therapy (testosterone undecanoate), trade name: AVEED.

Background/Discussion:

According to the requester, AVEED (testosterone undecanoate) Injection is the first and only long-acting testosterone replacement therapy (TRT) injection for hypogonadal men. AVEED is indicated for replacement therapy in adult males for primary hypogonadism and hypogonadrotropic hypogonadism. As an injection, AVEED has low risk of transference. AVEED provides an alternative TRT option to the currently available short-acting injectable and topical gels. AVEED is supplied in a single-use vial and is administered incident to a physician's service. Following the first intramuscular injection of 3 mL of AVEED (750/3mL), a second 3 mL dose is injected 4 weeks later and then 3 mL is injected every 10 weeks thereafter. It is available through a closed specialty distribution network and there is a Risk Evaluation and Mitigation Strategies, (REMS) Program for the product.

Preliminary Decision:

Establish JXXXX Injection, Testosterone Undecanoate, 1 mg

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #3

May 21, 2014

Attachment# 14.002

Topic/Issue:

Request to revise the text of existing code J7302 which currently reads: "Levonorgestrel-releasing intrauterine contraceptive system, 52mg" to instead read: "Levonorgestrel-releasing intrauterine contraceptive system (Mirena), 52mg".

Background/Discussion:

According to the requester, Mirena® (levonorgestrel-releasing intrauterine system) is an intrauterine contraceptive indicated to prevent pregnancy for up to five years and for the treatment of heavy menstrual bleeding. Mirena consists of a T-shaped polyethylene frame with a steroid reservoir around the vertical stem. Mirena is placed within the uterine cavity by a healthcare professional. Mirena contains 52mg of levonorgestrel released at a progressively decreasing rate over five years. It is supplied in a carton of one single-use sterile unit, which includes one Mirena contained within an inserter. Mirena must be removed by the end of the fifth year and can be replaced at the time of removal with a new Mirena. This request is to revise code J7302 in order to make it distinct from code J7301.

Preliminary Decision:

1) Do not revise code J7302. The proposed revision does not improve the code descriptor.

2) Revise the text of existing code J7301 to omit the word "(Skyla)". The revised code would read: "Levonorgestrel-Releasing Intrauterine Contraceptive System, 13.5mg".

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision. The speaker commented that if the brand name is removed from J7301 without adding a duration of use clause to codes J7301 and J7302, the likelihood of coding and billing errors will increase. The speaker recommended the following revised code text: J7302 "Levonorgestrel-releasing intrauterine contraceptive system, 52mg, **five years duration of use**"; and J7301 "Levonorgestrel-releasing intrauterine contraceptive system, 13.5mg, **three years of use**''.

HCPCS Public Meeting Agenda Item #4

May 21, 2014

Attachment# 14.047

Topic/Issue:

Request to establish a new Level II HCPCS code to identify injectable radiopharmaceutical Radium Ra 223 Dichloride, trade name: Xofigo. Applicants suggested language: Radium Ra 223 dichloride, therapeutic, per treatment dose.

Background/Discussion:

According to the requester, Xofigo® is an injectable therapeutic radiopharmaceutical containing radium Ra 223 dichloride. Radium Ra 223 dichloride provides targeted anti-tumor effect on bone metastases via alpha particle emission, and has a half-life of 11.4days. Xofigo® is indicated for the treatment of patients with castration resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease. It is dosed at 50 kBq (1.35 microcuries) per kg body weight, given at 4 week intervals for 6 injections. The safety and efficacy beyond 6 injections have not been studied. Xofigo® is administered as an intravenous injection (over one minute). It is manufactured and packaged in single use vials containing 6 mL of solution (1000 kBq/mL (27 microcurie/mL)); vial contains 6000 kBq (162 microcuries).

Preliminary Decision:

Establish AXXXX, Radium RA 223 Dichloride, Therapeutic, Per Microcurie

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker reiterated the original request for a "treatment dose" unit of measure. A "microcurie" unit of measure will result in a mismatch of the units used by providers and the units used by many payors to set reimbursement. According to the speaker, many payors that base reimbursement on AWP or WAC generally do not have a means of resolving this conflict in the units that would result if a microcurie-based dose descriptor is used. The speaker recommended "treatement dose" as the unit of measure.

HCPCS Public Meeting Agenda Item #5

May 21, 2014

Attachment# 14.056

Topic/Issue:

Request to modify the language of existing code J0135, which currently reads: "Injection, Adalimumab, 20mg"; to instead read: "Injection, Adalimumab, 20mg" (code may be used for Medicare when drug is administered under the direct supervision of a physician, not for use when drug is self-administered).

Background/Discussion:

According to the requester, HUMIRA® (adalimumab) is a recombinant human IgG1 monoclonal antibody specific for human tumor necrosis factor (TNF). HUMIRA is indicated for use in patients with rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and plaque psoriasis. HUMIRA is supplied as a sterile, preservative-free solution of adalimumab for subcutaneous administration in three types of presentations: 1) a single-use prefilled pen of 40mg of adalimumab intended for self-administration; 2) a single-use prefilled glass syringe of 20mg or 40mg of adalimumab intended for self-administration; and 3) a newly approved single-use glass vial of 40mg of adalimumab for institutional use only.

Preliminary Decision:

Existing code J0135 "Injection, Adalimumab, 20 mg" adequately describes the product that is the subject of this request. The proposed revision does not improve the code descriptor.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #6

May 21, 2014

Attachment# 14.045

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a sodium hyaluronate derivative, trade name: Monovisc™. Applicant's suggested language:

JXXXX Hyaluronan or Deriviative, Monovisc™, For Intra-Articular Injection, Per Dose.

Background/Discussion:

According to the requester, Monovisc is a single injection supplement to the synovial fluid of the osteoarthritic joint intended to provide symptomatic relief of joint pain. It is composed of a sterile, clear, biocompatible, restorable, viscoelastic fluid composed of partially cross-linked sodium hyalauronate (NaHA) solution in phosphate buffered saline. The product is cross-linked with a proprietary chemical cross-linker and manufactured from ultra-pure, high molecular weight sodium hyaluronate. Monovisc is administered via single intra-articular injection of 4.0mL. It is supplied in a pre-filled disposable glass 5mL syringe containing a 4mL dose of treatment (88mg Hyaluronan, 36mg Sodium Chloride, 0.8mg Potassium Chloride, 4.6mg. Potassium Phosphate, dibasic, 0.8mg Potassium Phosphate, Monobasic, and USP water for injection. Monovisc is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmagologic therapy and simple analgesics, (e.g. acetaminophen).

Preliminary Decision:

Establish JXXXX Hyaluronan or Derivative, Monovisc, For Intra-Articular Injection, Per Dose

Summary of Primary Speaker Comments at the Public Meeting:

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

HCPCS Public Meeting Agenda Item #7

May 21, 2014

Attachment# 14.003
Topic/Issue:

Request to establish a new Level II HCPCS code to identify a radioactive diagnostic agent for PET imaging, Florbetapen (18F), trade name: Neuraceq. Applicant's suggested language:

AXXXX Injection, Florbetaben 18F, diagnostic, per study dose, up to 8.1 millicures.

Background/Discussion:

According to the requester, Neuraceq (Florbetaben (18f)), is a diagnostic radiopharmaceutical used with Positron Emission Tomography (PET) Imaging to detect B-Amyloid neuritic plaques in the brain, a leading indicator of Alzheimer's disease (AD), in adults suffering from mild cognitive impairment. A unique HCPCS code is needed in order to differentiate Neuraceq from other beta-amylod radiopharmaceuticals that may be used in PET imaging under CMS' coverage with evidence development requirements. A unique code will also allow researchers to analyze critical data to determine the effects of specific imaging agents, and facilitate accurate payment in settings where diagnostic radiopharmaceuticals are separately billed.

Preliminary Decision:

Existing code A9599 "Radiopharmaceutical, Diagnostic, For Beta-Amyloid Positron Emission Tomography (PET) Imaging, Per Study Dose" adequately describes the product that is the subject of this request.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision not to establish a HCPCS code. The speaker stated while there have been no head-to-head comparative studies between Beta Amyloid agents, there are differences in chemical structures, kinetic properties, applied dose, image acquisition time, visual assessment method and overall radiation exposure, which may be significant, and requires individual codes for differentiation. HCPCS codes for each agent will aid researchers in tracking and analyzing clinical data using commonly available Medicare claim information. The speaker stated that without the ability to readily and easily differentiate between agents, it will be difficult for researchers and CMS to determine a class-wide coverage decision. The speaker reiterated the original request for a unique code.

HCPCS Public Meeting Agenda Item #8

May 21, 2014

Attachment# 14.048

Topic/Issue:

Request to modify existing code J7335 which currently reads: "Capsaicin 8% Patch, Per 10 Square Centimeters" to instead read: "Capsaicin 8% Patch, Per Patch".

Background/Discussion:

According to the requester, QUTENZA is the first and only concentrated, synthetic capsaicin-containing prescription drug to undergo FDA review. QUTENZA contains capsaicin in a localized dermal delivery system consisting of backing film coated with capsaicin-containing adhesive. Each single-use QUTENZA patch is 14 cm x 20 cm containing 179 mg of capsaicin. QUTENZA is indicated for the management of neuropathic pain associated with postherpetic neuralgia (PHN). It is applied directly to skin at the site of pain. Only physicians or health care professionals under the close supervision of a physician are to administer QUTENZA. It is supplied one-patch carton or two-patch carton, each with a 50 g tube of cleansing gel. The requester is seeking a descriptor change that would "result in a per patch billing unit, which better aligns with the product label and alleviates provider confusion.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to modify the dose descriptor of existing code J7335. The proposed revision does not improve the code descriptor.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision and recommended that the descriptor for code J7335 be modified from "capsaicin 8% patch, per 10 square centimeters" to "capsaicin 8% patch, per patch". The modification will align the billing unit with Qutenza's FDA-approved label and package size, and help avoid billing confusion.

HCPCS Public Meeting Agenda Item #9

May 21, 2014

Attachment# 14.033

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Coagulation Factor IX [Recombinant], trade name: Rixubis. Applicant's suggested language:

JXXXX Factor IX (Antihemophilic Factor, Recombinant), Rixibus, Per IU.

Background/Discussion:

According to the requester RIXUBIS [COAGULATION FACTOR IX (RECOMBINANT)] is for adults with hemophilia B. RIXUBIS is the only recombinant factor IX indicated to treat adults with hemophilia B for: routine prophylaxis to prevent or reduce the frequency of bleeding episodes, control and prevention of bleeding episodes and perioperative management. RIXIBUS is supplied in 5-mL diluent vials in 5 dosage strengths: 250 IU, 500 IU, 1000 IU, 2000 IU and 3000 IU.

Preliminary Decision:

Establish JXXXX Injection, Factor IX, (Antihemophilic Factor, (Recombinant)), Rixubus, Per IU.

HCPCS code C9133 "Factor IX (antihemophilic factor, recombinant), Rixubis, per IU" is available for assignment by insurers until such time as a J code would be established.

Revise J7195 which currently reads "Factor IX (antihemophilic factor, recombinant) per IU "to read "Factor ix (antihemophilic factor, recombinant) per IU, Not Otherwise Specified".

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #10

May 21, 2014

Attachment# 14.055

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a typical antipsychotic, Loxapine, trade name: Adasuve. Applicant's suggested language:

JXXXX Loxapine, Inhalation Powder, 10mg.

Background/Discussion:

According to the requester, ADASUVE® (loxapine) inhalation powder is a typical antipsychotic indicated for the acute treatment of agitation associated with schizophrenia or bipolar 1 disorder in adults. As part of the ADASUVE Readiness and Emergency Management, (REMS) Program to mitigate the risk of bronchospasm, ADASUVE must be administered only in an enrolled healthcare facility. ADASUVE is supplied in a single-use, disposable inhaler containing 10 mg of loxapine base. It provides rapid systemic delivery by inhalation of a thermally-generated aerosol of loxapine. According to the requester, there are no J codes to describe this formulation and delivery method for loxapine. Only 1 dose should be administered within a 24-hour period.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a new HCPCS code to identify the product that is the subject of this request. Existing code C9497 "Loxapine, Inhalation Powder, 10mg", is available for assignment by insurers if they deem appropriate.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #11

May 21, 2014

Attachment# 14.051

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify solvent/detergent treated pooled human plasma, trade name: Octaplas®. Applicant's suggested language: Injection, pooled Plasma (Human), Solvent/detergent treated (Octaplas), 200mL. OR, if a new code is not established, the applicant requests a change in reimbursement level for existing code P9023.

Background/Discussion:

According to the requester, Octaplas® (Pooled Plasma (Human), Solvent/Detergent Treated Solution for infusion) was FDA approved for 1) replacement of multiple coagulation factors in patients with acquired deficiencies due to liver disease or for patients undergoing cardiac surgery or liver transplant; and for 2) plasma exchange in patients with thrombotic thrombocytopenic purpura (TTP). The product is supplied as a solution for infusion containing 45 to 70 mg human plasma protein per mL in a 200 mL volume. The dose is typically 10 to 15 mL per kg for the first indication, and 40 to 60 mL per kg for the second. Octaplas® is for intravenous use only and should be administered based on ABO-blood group compatibility. The requester comments that Octaplas should be coded as a drug/biologic or that the reimbursement level for P9023 be amended to reflect the price of the marketed product.

Preliminary Decision:

Existing code P9023 "Plasma, Pooled Multiple Donor, Solvent/Detergent Treated, Frozen, Each Unit" adequately describes the product that is the subject of this request. Inquiries regarding payment should be submitted directly to the insurer in whose jurisdiction a claim would be filed.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to establish a unique HCPCS code. The speaker stated that Octaplas does not meet CMS' definition of a blood product. Therefore a "P" code is inappropriate. Octaplas was approved by the FDA "pursuant to a biologic (BLA) request". Other entities treat Octaplas as a pharmaceutical, and as such, the speaker is recommended a "J"code.

HCPCS Public Meeting Agenda Item #12

May 21, 2014

Attachment# 14.036

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a monoclonal antibody, obinutuzumab, trade name: Gazyva. Applicant's suggested language:

JXXXX Injection, Obinutuzumab, 100mg.

Background/Discussion:

According to the requester, GAZYVA is glycoengineered type II humanized anti-CD20 monoclonal antibody. It is indicated in combination with chlorambucil, for the treatment of patients with previously untreated Chronic Lymphocytic Leukemia, (CLL). GAZYVA targets the CD20 antigen expressed on the surface of pre B- and mature B-lymphocytes. Upon binding to CD20, GAZYVA mediates B-cell lysis through 1) engagement of immune effector cells, 2) by directly activating intracellular death signaling pathways and/or 3) activation of the complement cascade. The immune effector cell mechanisms include antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis. GAZYVA is supplied at a concentration of 25mg/mL in 1000 mg single-use vials. It is administered as an intravenous infusion in fixed doses, and does not have weight-based dosing. GAZYVA is administered on days 1, 2, and 8 and 15 of the first 28-day cycle of treatment and day 1 subsequent cycles, for up to six (6) 28-day cycles in total. In the first cycle of treatment, 100mg is given on day 1, and 900mg on day 2. For days 8 and 15 of cycle 1 and for day 1 of all subsequent 28-day cycles (cycles 2-6), the dose is 1000mg per administration.

Preliminary Decision:

Establish JXXXX Injection, Obinutuzumab, 10 mg

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #13

May 21, 2014

Attachment# 14.034

Topic/Issue:

Request to establish a new Level II HCPCS code to identify ferric carboxymaltose iron replacement, trade name: Injectafer. Applicant's suggested language:

JXXXX Injection, Ferric Carboxymaltose, 1mg.

Background/Discussion:

According to the requester Injectafer® is a non-dextran iron replacement formulation approved for the treatment of Iron Deficiency Anemia (IDA) in adult's patients who have intolerance to oral iron or have had an unsatisfactory response to oral iron, and for non-dialysis dependent patients with Chronic Kidney Disease (CKD). The code should be specific for Injectafer® so that providers, Medicare Contractors and insurers do not confuse ferric carboxymaltose injection with codes for other iron replacement products. Injectafer may be given as a single injection of up to 750 mg, at a rate of approximately 100mg/minute on two occasions separated by at least 7 days up to a cumulative dose of 1,500 mg of iron. Injectafer is supplied in vials containing 50mg elemental iron per mL as: 750mg iron/15mL individually boxed in a package of 2 vials.

Preliminary Decision:

Existing code Q9970 "Injection, Ferric Carboxymaltose, 1mg", adequately describes the product that is the subject of this request.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item #14

May 21, 2014

Attachment# 14.013

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Low Nitrogen 1% Polidocanol Injectable foam, trade name: Varithena™. Applicant's suggested language:

JXXXX Low Nitrogen 1% Polidocanol Injectable foam; Sterile canister, 1ml.

Background/Discussion:

According to the requester Varithena™ is a sclerosing agent indicated for the treatment of incompetent great saphenous veins (GSV), and visible varicosities of the GSV system above and below the knee. Varithena™ is intended for intravenous injection using ultrasound guidance, administered via a single cannula into the lumen of the target incompetent trunk vein or by direct injection into varicosities. The maximum volume of Varithena™ per treatment session is 15mL. The actual volume injected will vary with the size/extent of the varicose veins to be treated. Varithena™ is supplied in a sterile multi-use canister; which upon activation generates 45 mL of usable foam. Once it is activated it is a white injectable foam sclerosing agent, which comprises 1% polidocanol solution (a non-ionic surfactant) and a gas mixture of oxygen: carbon dioxide in a ratio of 65:35 with low (<0.8%) nitrogen content. Once Varithena™ is activated it must be used within seven days. Varithena™ is the first FDA-approved drug/device combination product that generates injectable foam. The foam is generated from a proprietary canister system and is composed of gas and liquid phase. The foam displaces blood from the target vein and the polidocanol within the foam scleroses the endothelium. No existing HCPCS code adequately describes Varithena™.

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private Insurance sector to establish a HCPCS code to identify Varithena.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to establish a HCPCS code. Varithena is the first FDA approved drug for GSV system incompetence and is distinct from "physician home-made" (compounded) foams which can cause stroke or heart attack. The speaker reiterated the original request for a "J" code for Varithena.

HCPCS Public Meeting Agenda Item #15

May 21, 2014

Attachment# 14.006

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a local anesthetic administered into a surgical site, (bupivacaine liposome injectable suspension), trade name: Exparel.

Background/Discussion:

According to the requester, EXPAREL® (bupivacaine liposome injectable suspension), is an amide-type local anesthetic, indicated for single-dose local administration into the surgical site to produce postsurgical analgesia. The analgesic benefit has been demonstrated to last up to 72 hours while decreasing opioid requirements. Practitioners may not report C9290 for office-based use. The applicant states that currently, J3490 is reported in the physician office setting. Therefore, a new J code is needed to replace J3490 to describe EXPAREL for office-based use. The recommended dose of EXPAREL is based on the surgical site and the volume required. The maximum dose is 266 mg (20 mL). EXPAREL is supplied in a 20 mL single-use vial. Because of the unique liposome delivery system that differentiates EXPAREL from other anesthetics, there are no other identical products.

Preliminary Decision:

Existing code C9290, "Injection Bupivacaine Liposome, 1 mg" adequately describes the product that is the subject of this request, and is available for assignment by insurers if they deem appropriate A national program operating need to establish a HCPCS Level II "J" code for Physician's office use was not identified by Medicare, Medicaid or the Private Insurance sector When this product is used in a physician's office, it is part of the surgical procedure and is included in the practice expense. Therefore, separate billing would be duplicative.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to establish another HCPCS code. Exparel provides postsurgical pain control for several days. It reduces or eliminates the need for other prescribed pain management treatments such as opioids that are typically paid separately from surgical procedures and are generally obtained as a prescription/covered by the patient's prescription benefit. The pass-through payment for Exparel is sun-setting, and a new HCPCS code with a separate fee should be established.

HCPCS Public Meeting Agenda Item #16

May 21, 2014

Attachment# 14.042

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Kcentra, and to discontinue existing code C9132, (which describes Kcentra). Applicant's suggested language:

JXXXX Kcentra Prothrombin Complex Concentrate, Kcentra, Each Factor IX IU

Background/Discussion:

According to the requester, Kcentra™, Prothrombin Complex Concentrate (Human), a designated orphan drug, is a blood coagulation factor replacement product indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA) therapy in adult patients with acute major bleeding or need of urgent surgery or invasive procedure. Kcentra restores vitamin K deficient blood clotting factors. Kcentra dosing is based on the patient's baseline International Normalized Ratio (INR) value and body weight up to but not exceeding 100kg. Kcentra is available as lyophilized powder which is reconstituted with sterile water prior to administration via intravenous infusion. It is supplied as a single-use vial containing a mixture of Factors II, VII, IX, and X, proteins C and S as a lyophilized concentrate for reconstitution. Kcentra potency is defined by Factor IX content. The range of Factor IX units per vial is 400-620 units for the 500 U kit (500 u in 20 mL sterile water for injection); and 800-1240 units for the 1000 u kit (1000 u in 40mL sterile water for injection). The applicant comments that a "J" code would permit uniform billing in applicable care settings, whereas the C-code "restricts use to Medicare Hospital Outpatient Settings".

Preliminary Decision:

A national program operating need was not identified by Medicare, Medicaid or the Private insurance sector to establish another Level II HCPCS code to identify Kcentra. Existing code C9132 "Prothrombin Complex Concentrate (Human), Kcentra, Per IU of Factor ix Activity", adequately describes the product that is the subject of this request, and is available for assignment by insurers if they deem appropriate.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to establish another HCPCS code. A "J" code would accommodate the use of Kcentra "entities that bill as physician offices". "C" codes do is not meet the needs of non-Medicare payers and cannot be used in physician offices or other freestanding settings.

HCPCS Public Meeting Agenda Item #17

May 21, 2014

Attachment# 14.049

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an optical imaging agent, hexaminolevulinate hydrochloride, trade name: Cysview. Applicant's suggested language:

JXXXX Injection, Hexaminolevulinate Hydrochloride For Intravesical Instillation, 100mg.

Background/Discussion:

According to the requester, CYSVIEW® is used to perform the Blue Light Cystoscopy procedure on patients suspected or known to have cancerous lesions of the bladder on the basis of a prior (white light) cystoscopy. CYSVIEW® (100mg powder) is reconstituted into a 50mL solution and instilled into the bladder via a urinary catheter prior to the cystoscopy procedure. CYSVIEW® with Blue Light Cystoscopy provides early and accurate detection of non-muscle invasive bladder tumors, which can potentially lead to improved treatment for patients, and a reduction of recurrence. The recommended dose for adults is 50mL of reconstituted solution containing 100mg of CYSVIEW®, instilled into the bladder (intravesical instillation) via a urinary catheter. The requester is seeking a new code to enable separate reimbursement for the administration of Cysview when used in an office setting.

Preliminary Decision:

Existing code C9275 "Injection, Hexaminolevulinate Hydrochloride, 100 mg, Per Study Dose", adequately describes the product that is the subject of this request, which is used in the performance of a diagnostic test.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to establish another HCPCS code stating that code C9275 is accepted only by Medicare outpatient/ASC settings, and is not accepted by Medicare in physician office settings. The speaker stated, urologists want to be able to provide Cysview with blue light cystoscopy in the office, they don't want to invest in the technology without an established coding pathway to separate reimbursement. The speaker reiterated the original request for a "J" code.

HCPCS Public Meeting Agenda Item #18

May 21, 2014

Attachment# 14.004

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an enzyme replacement therapy for Mucopolysaccharidosis type IVA; elosulfase alfa, trade name: VIMIZIM. Applicant's suggested language:

JXXXX Injection, Elosulfase Alfa For Intravenous Infusion, 1mg.

Background/Discussion:

According to the requester Vimizim is an enzyme replacement therapy for the treatment of Mucopolysaccharidosis type IVA (also known as Morquio A or MPS IVA), an inherited, autosomal recessive disease caused by a deficiency in the activity of the lysosomal enzyme N-acetylgalactosamine 6-sulfatase (GALNS). Vimizim treats this disease by providing a recombinant version of this enzyme. It is supplied as a concentrated solution for infusion (1mg per mL) requiring dilution. The recommended dose for Vimizim is 2mg per kg body weight administered once a week via intravenous infusion over approximately 4 hours. Pre-treatment with antihistamines with or without antipyretics is recommended 30-60 minutes prior to start of infusion.

Preliminary Decision:

Establish JXXXX, Injection, Elosulfase Alfa, 1mg

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for the item.

HCPCS Public Meeting Agenda Item #19

May 21, 2014

Attachment# 14.001

Topic/Issue:

Request to establish a new Level II HCPCS code to identify TRETTEN® Coagulatin Factor XIII (recombinant). Applicant's suggested language:

JXXXX Injection Factor XIII (Tretten Coagulation Factor XIII A-Subunit (Recombinant)), Per IU.

Background/Discussion:

According to the requester, Factor XIII enzyme's role in maintaining a blood clot is through cross-linking fibrin and other proteins in the fibrin clot. TRETTEN® is a unique, single source biologic, and recombinant clotting factor product. TRETTEN® Coagulation Factor XIII A Subunit (Recombinant) is prescribed as monthly replacement therapy for patients with Congenital FXIII deficiency (A-subunit) and has been shown to have the same pharmacodynamics properties in plasma as endogenous FXIII, the terminal enzyme in the blood coagulation cascade. TRETTEN® is supplied as a lyophilized powder in a single-use containing 2000-3125 IU Coagulation Factor XIII A Subunit (Recombinant) and is delivered as a monthly intravenous infusion. The recommended dose is 35 IU/kg.

Preliminary Decision:

Establish J71XX, Injection, Factor XIII A-Subunit, (Recombinant), Per 10 IU

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker agreed with CMS' preliminary decision to establish a "J" code, but recommended the dose descriptor be "per IU"; instead of "per 10 IU".

HCPCS Public Meeting Agenda Item #20

May 21, 2014

Attachment# 14.008

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Novoeight® Antihemophilic factor VIII (Recombinant). Applicant's suggested language:

JXXXX Injection, factor VIII (Novoeight® Antihemophilic factor (Recombinant)), Per IU.

Background/Discussion:

According to the requester, Novoeight®, Antihemophilic Factor (Recombinant), is indicated for use in adults and children with hemophilia A (congenital factor VIII deficiency or classic hemophilia) for control and prevention of bleeding episodes; perioperative management; and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Novoeight® temporarily replaces the missing clotting factor VIII that is needed for effective hemostasis in patients with congenital hemophilia A. Novoeight® is for intravenous use only. Novoeight® is supplied as lyophilized powder in single-use vials; one vial per carton; containing 250, 500, 1000, 1500, 2000 or 3,000 IU. The required dosage is determined using the following formula: Dosage Required (IU) =Body Weight (kg) x Desired Factor VIII Increase (IU/dL or % normal) x 0.5 (IU/kg per IU/dL).

Preliminary Decision:

Establish, JXXXX, Factor VIII, (Antihemophilic Factor, (Recombinant)), (Novoeight), Per IU

Summary of Primary Speaker Comments at the Public Meeting:

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

HCPCS Public Meeting Agenda Item #21

May 21, 2014

Attachment# 14.007

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Flutemetamol F18 injection, trade name: Vizamy™. Applicant's suggested language:

AXXXX Flutemetamol F18, Diagnostic, Per Study Dose, Up To 5 Millicuries.

Background/Discussion:

According to the requester Vizamyl is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the brain to estimate Bamyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) or other causes of cognitive decline. The recommended dose for Vizamyl is 185 megabecquerels (MBq) [5 millicuries (mCi)] in a maximum dose volume of 10 mL, administered as a single intravenous bolus within 40 seconds. The maximum mass dose is 20 micrograms. Vizamyl injection is available in 10-mL or 30-mL multi-dose vial.

Preliminary Decision:

Existing code A9599, "Radiopharmaceutical, Diagnostic, For Beta-Amyloid Positron Emission Tomography (PET) Imaging, Per Study Dose" adequately describes the product that is the subject of this request.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant disagreed with CMS' preliminary decision not to establish a unique HCPCS code to identify Vizamyl. The speaker stated that there is no HCPCS code that accurately denotes this product that is used in Positron Emission Tomography (PET) imaging. The speaker also commented that it is essential that CMS and commercial payers acquire high quality data on these new innovative drugs. The speaker recommended a new unique "A" code for Vizamy.

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 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 - These are injectable or intravenous drugs as well as non-injectable or non-intravenous drugs that are administered incident-to a physician's service. Under the “incident-to” provision, the physician must incur a cost for the drug, and must also 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 - These are DME drugs are administered through a covered item of DME, such as a nebulizer or a pump; and
- Drugs covered by statute - These are drugs specifically covered by statute including 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 (FQHCs).

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 (AWP). 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 the 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 (NDCs) 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

Medicare pays a **dispensing fee** to a pharmacy for inhalation drugs furnished through DME, a **supplying fee** 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, or 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.

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.

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