

**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.

**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.

**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".

**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.

**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).

**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.

**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 millicuries.

**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".

**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.

**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.

**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.

**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.

**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.

**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.

**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.

**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

**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.

**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.

**AGENDA ITEM #19**

Attachment# 14.001

Request to establish a new Level II HCPCS code to identify TRETEN® Coagulation Factor XIII (recombinant). Applicant's suggested language: JXXXX Injection Factor XIII (Tretten Coagulation Factor XIII A-Subunit (Recombinant)), Per IU.

**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.

**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.

## 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.

## 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 hypogonadotropic 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

## 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".

## 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

## 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.

## 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 Derivative, 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 hyaluronate (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 nonpharmacologic therapy and simple analgesics, (e.g. acetaminophen).

### **Preliminary Decision:**

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

## 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 millicuries.

### **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-amyloid 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.

## 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.

## 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)), Rixibus, 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".

## 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.

## 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 (Octoplas), 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.

## 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

## 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.

## 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.

## 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.

## 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.

## 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.

## 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

## 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 TRETEN® Coagulation 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. TRETEN® is a unique, single source biologic, and recombinant clotting factor product. TRETEN® 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. TRETEN® 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 Factor XIII A-Subunit, (Recombinant), 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

## 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.

