Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Agenda
for Drugs, Biologicals and Radiopharmaceuticals
Friday, May 8, 2015 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# 15.002
Request to establish a new Level II HCPCS code to identify Beleodaq® (belinostat).
Applicant's suggested language: JXXXX-injection, belinostat, 500mg.

AGENDA ITEM #2
Attachment#15.022
Request to establish a unique Level II HCPCS code to identify Blincyto® (blinatumomab).
Applicant's suggested language: JXXXX - Injection, blinatumomab, 1 mcg.

AGENDA ITEM #3
Attachment# 15.007
Request to establish a unique Level II HCPCS code to identify Cyramza® (ramucirumab).
Applicant's suggested language: J9XXX –"injection, ramucirumab, 1 mg"

AGENDA ITEM #4
Attachment# 15.004
Request to establish a unique Level II HCPCS code to identify Lemtrada™ (alemtuzumab). Applicant's suggested language: JXXXX Alemtuzumab, per 1 mg, (*not* in the J9XXX series).

AGENDA ITEM #5
Attachment# 15.018
Request to establish a unique Level II HCPCS code to identify AKYNZEO (netupitant and palonosetron) capsules. Applicant's suggested language: JXXXX - netupitant and palonosetron, oral, 300 mg/0.5 mg.

AGENDA ITEM #6
Attachment# 15.019
Request to establish a unique Level II HCPCS code to identify Sylvant® (siltuximab). Applicant's suggested language: JXXXX - Injection, siltuximab, per 100 mg.

AGENDA ITEM #7
Attachment#15.031
Request to create a unique Level II HCPCS code to identify RAPIVAB™ (peramivir injection). Applicant's suggested language: JXXXX - Injection, peramivir, 200 mg

AGENDA ITEM #8
Attachment# 15.028
Second request to establish a unique Level II HCPCS code to identify Recombinant C1 Esterase Inhibitor, Trade Name: RUCONEST. Applicant's suggested language: JXXXX - Injection, C-1 Esterase Inhibitor (Recombinant) [RUCONEST], per unit (1vial)

AGENDA ITEM #9
Attachment# 15.035
Request to establish a unique Level II HCPCS Code to identify (carbidopa and levodopa) enteral suspension, Trade Name: DUOPA™. Applicant's suggested language: JXXXX - DUOPA™ (carbidopa and levodopa enteral suspension 1:4 ratio), per 5 mg carbidopa and 20 mg levodopa

AGENDA ITEM #10
Attachment# 15.036
Request to establish a new Level II HCPCS code to identify sulfur hexafluoride, lipid-type-A microspheres injectable suspension, Trade Name: Lumason. Applicant's suggested language: QXXXX Injection, sulfur hexafluoride lipid microspheres, per ml

AGENDA ITEM #11
Attachment# 15.020
Request to establish a unique Level II HCPCS code to identify ferric pyrophosphate citrex solution, Trade Name: TRIFERIC®. Applicant's suggested language: JXXXX - TRIFERIC® (ferric pyrophosphate citrex) solution; 5.44 mg of iron per ml.

AGENDA ITEM #12
Attachment# 15.029
Request to establish a unique Level II HCPCS code to identify ceftolozane/tazobactam, ZERBAXA™. Applicant's suggested language: JXXXX Injection, ceftolozane/tazobactam, 1.5g.

AGENDA ITEM #13
Attachment#15.030
Request to establish a unique Level II HCPCS code to identify tedizolid phosphate, Sivextro™. Applicant's suggested language: JXXXX - Injection, tedizolid phosphate, 200 mg

AGENDA ITEM #14
Attachment# 15.034
Request to establish a unique Level II HCPCS code to identify Keytruda® (pembrolizumab). Applicant's suggested language: J9XXX - Injection, pembrolizumab, 1 mg.

AGENDA ITEM #15
Attachment# 15.046
Request to establish a unique Level II HCPCS code to identify OPDIVO® (nivolumab). Applicant's suggested language: J9XXX - Injection, nivolumab, 1 mg

AGENDA ITEM #16
Attachment# 15.038
Request to establish a unique Level II HCPCS code to identify Signifor® (LAR), (pasireotide). Applicant's suggested language: JXXXX- injection, pasireotide long acting, 1 mg

AGENDA ITEM #17
Attachment# 15.041
Request to establish a unique Level II HCPCS code to identify DALVANCE (dalbavancin). Applicant's suggested language: JXXXX - Injection, dalbavancin, 10 mg.

AGENDA ITEM #18
Attachment# 15.032
Request to revise the descriptor of existing code J7302 to add brand name and duration of use. Applicant's suggested language: Revise existing code J7302 which currently reads: "Levonorgestrel- releasing intrauterine contraceptive system, 52 mg"; to instead read: "Levonorgestrel- releasing intrauterine contraceptive system (Mirena), 52 mg, five years duration of use".

AGENDA ITEM #19
Attachment# 15.009
Request to establish a unique Level II HCPCS code to identify a new drug, Iluvien®, (fluocinolone acetonide intravitreal implant 0.19 mg). Applicant's suggested language: JXXXX- injection, fluocinolone acetonide, ILUVIEN, intravitreal implant, 0.19 mg.

AGENDA ITEM #20
Attachment# 15.010
Request to establish a unique Level II HCPCS code to identify Entyvio® (vedolizumab). Applicant's suggested language: JXXXX - injection, vedolizumab, 1 mg.

AGENDA ITEM #21
Attachment# 15.012
Request to establish a unique Level II HCPCS code to identify a new sodium hyaluronate for injection, Gel-Syn™. Applicant's suggested language: J732XX - Hyaluronan or Derivative, Gel-Syn, For Intra-Articular Injection, Per Dose.

AGENDA ITEM #22
Attachment# 15.016
Request to establish another Level II HCPCS code to identify Orbactiv™ (oritavancin). Applicant's suggested language: JXXXX - Injection, oritavancin, 10 mg. This descriptor is consistent with the C-code recently issued for Orbactiv, C9444, Injection, oritavancin, 10 mg.

AGENDA ITEM #23
Attachment# 15.015
Request to establish a new Level II HCPCS code to identify a renal replacement solution, Trade name: Phoxillum. Applicant's suggested language: "JXXXX Renal Replacement Solution (Phoxillum), 5000 ml"

AGENDA ITEM #24
Attachment# 15.013
Request to establish a Level II HCPCS code to identify immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase, HYQVIA™, for subcutaneous administration only. Applicant's suggested language: JXXXX - Injection, Immune Globulin, (HYQVIA), 100 mg.

AGENDA ITEM #25
Attachment# 15.014
Request to establish a unique Level II HCPCS code to identify Antihemophilic Factor (Recombinant), Porcine Sequence, Obizur™. Applicant's suggested language: JXXXX - Injection, Factor VIII (Antihemophilic Factor, Recombinant, Porcine Sequence), (Obizur), Per IU.

AGENDA ITEM #26
Attachment# 15.001
Request to establish a new level II HCPCS code to describe Fc fusion protein antihemophilic recombinant Factor VIII, brand name, Eloctate™. Applicant's suggested language: JXXXX Injection, Factor VIII (Antihemophilic Factor, Recombinant, Fc Fusion) (Eloctate™), Per IU

AGENDA ITEM #27
Attachment# 15.027
Third request to establish a unique Level II HCPCS code to identify injectable Epoprostenol Sodium, Velitri®. Applicant's suggested language: JXXXX Injection, Epoprostenol, Saline Diluent, Velitri, 0.5 mg

AGENDA ITEM #28
Attachment# 15.039
Request to establish a unique Level II HCPCS code to identify Cresemba (isavuconazonium) for intravenous infusion. Applicant's suggested language: isavuconazonium, intraveneous, per 1 mg.

AGENDA ITEM #29
Attachment# 15.017
Request to establish a Level II HCPCS code to identify Avycaz™ (Ceftazidime-Avibactam). Applicant's suggested language: JXXXX - Injection, Ceftazidime-Avibactam, 2g/500mg.

HCPCS Public Meeting Agenda Item #1

May 8, 2015

Attachment# 15.002

Topic/Issue:

Request to establish a new Level II HCPCS code to identify Beleodaq® (belinostat). Applicant's suggested language: JXXXX-injection, belinostat, 500mg.

Background/Discussion:

Spectrum Pharmaceuticals, Inc. submitted a request to establish a HCPCS code to identify BELEODAQ. According to the requester, BELEODAQ is a histone deacetylase (HDAC) inhibitor indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This indication is approved under the accelerated approval based on tumor response rate and duration of response. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication maybe contingent upon verification and description of clinical benefit in the confirmatory trial. HDACs catalyze the removal of acetyl groups from the lysine residues of histones and some non-histone proteins. In *vitro,* belinostat caused the accumulation of acetylated histones and other proteins, inducing cell cycle arrest and/or apoptosis of some transformed cells. Belinostat shows preferential cytotoxicity towards tumor cells compared to normal cells.

The recommended dosage of BELEODAQ is 1,000 mg/m^2 administered over 30 minutes by intravenous infusion once daily on days 1-5 of a 21-day cycle. Cycles can be repeated every 21 days until disease progression or unacceptable toxicity. Treatment discontinuation or interruption with or without dosage reductions by 25% may be needed to manage adverse reactions. BELEODAQ for injection is supplied in single vial carton; each 30 mL clear vial contains sterile lyophilized powder equivalent to 500 mg belinostat.

The requester comments that there are no existing HCPCS codes to report the use of BELEODAQ in the physician's office.

Preliminary Decision:

Establish JXXXX Injection, Belinostat, 10mg

HCPCS Public Meeting Agenda Item #2

May 8, 2015

Attachment# 15.022

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify Blincyto® (blinatumomab). Applicant's suggested language: JXXXX - Injection, blinatumomab, 1 mcg.

Background/Discussion:

Amgen, Inc. submitted a request to establish a HCPCS code to identify Blincyto®, a bispecific CD19-directed CD3 T-cell engager that binds to CD19 expressed on the surface of cells of B-lineage origin and CD3 expressed on the surface of T-cells. It activates endogenous T-cells by connecting CD3 in the T-cell receptor (TCR) complex with CD19 on benign and malignant B cells. Blinatumomab mediates the formation of a synapse between the T-cell and the tumor cell, upregulation of cell adhesion molecules, production of cytolytic proteins, release of inflammatory cytokines, and proliferation of T-cells, which result in redirected lysis of CD19+ cells. Blincyto is indicated for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials. A single treatment cycle includes 4 weeks of continuous IV infusion followed by a 2-week treatment-free interval. In cycle 1, Administer 9 mcg/day on days 1-7; and 28 mcg/day on days 8-28. For subsequent cycles, administer 28 mcg/day on days 1-28. A treatment course includes up to 2 cycles for induction, then 3 more cycles for consolidation treatment (up to 5 cycles, total). To help reduce infusion reactions, pre-medicate with dexamethasone 20 mg IV 1 hour prior to first dose of Blincyto of each cycle; each step dose (e.g., cycle 1 day 8); and when restarting infusion after interruption of 4 hours or more. Administer Blincyto as a continuous IV infusion at a constant flow rate using a programmable, lockable, non-elastomeric pump that has an alarm. Because alteration in flow rate can change dosage, patients should contact their care provider immediately, when there are issues with the pump. The IV bag must be changed at least every 24-48 hours by a health care professional.

Blincyto is supplied in a single-use vial containing 35 mcg of lyophilized powder that is reconstituted for IV administration. The package also includes an IV solution stabilizer, used to coat IV bags prior to the addition of reconstituted Blincyto.

According to the applicant, no current HCPCS codes specifically describe BLINCYTO.

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 C9449 is available for assignment by insurers if they deem appropriate.

HCPCS Public Meeting Agenda Item #3

May 8, 2015

Attachment# 15.007

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify Cyramza® (ramucirumab). Applicant's suggested language: J9XXX –"injection, ramucirumab, 1 mg"

Background/Discussion:

Eli Lilly & Co. submitted a request to establish a new HCPCS code to identify Cyramza. According to the requester, Cyramza is a vascular endothelial growth factor receptor 2 (VEGFR2) antagonist that specifically binds VEGF Receptor 2 and blocks binding of VEGFR ligands, VEGF-A, VEGF-C, and VEGF-D. As a result, Cyramza inhibits ligand-stimulated activation of VEGF Receptor 2, thereby inhibiting ligand-induced proliferation, and migration of human endothelial cells. Cyramza as a single agent, or in combination with paclitaxel, is used in the treatment of patients with advanced or metastatic, gastric or gastro-esophageal junction adenocarcinoma with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy. Cyramza increases the risk of hemorrhage, including severe and sometimes fatal hemorrhagic events and should be permanently discontinued in patients who experience severe bleeding.

The recommended dose of Cyramza either as a single agent or in combination with weekly paclitaxel is 8 mg/kg every 2 weeks administered as an ibtravenous infusion over 60 minutes. Continue Cyramza until disease progression or unacceptable toxicity. When given in combination, CYRAMZA should be administered prior to administration of paclitaxel. CYRAMZA shouldn't be administered as an intravenous push or bolus.

Cyramza is supplied in 100 mg/10 ml and 500 mg/50 ml single-use vials.

According to the requester, there is a pass-through code to identify Cyramza used in a hospital outpatient setting, but no existing code that describes Cyramza for use in a physician's office.

Preliminary Decision:

Establish JXXXX Injection, Ramucirumab, 5mg

HCPCS Public Meeting Agenda Item #4

May 8, 2015

Attachment# 15.004

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify Lemtrada™ (alemtuzumab). Applicant's suggested language: JXXXX Alemtuzumab, per 1 mg, (*not* in the J9XXX series).

Background/Discussion:

The Genzyme Corporation submitted a request to establish a code to identify Lemtrada. According to the requester, Lemtrada is a recombinant DNA-derived humanized monoclonal antibody that binds to CD52 and depletes circulating T and B lymphocytes. It is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Lemtrada is available only via a restricted program under a Risk Evaluation and Management Strategy (REMS), as it causes serious and life-threatening auto-immune conditions; infusion reactions; and malignancies. Due to its safety profile, Lemtrada should be reserved for patients who have had inadequate response to two or more drugs indicated for the treatment of MS. In accordance with the REMS Program, to assure safe use, Lemtrada may only be administered by healthcare practitioners who are trained in using the REMS Program Overview and education program for healthcare facilities. Lemtrada may only be administered in heathcare settings with current REMS certification that have on-site access to equipment and personnel trained to manage infusion reactions (including anaphylaxis and cardiac and respiratory emergencies). Lemtrada is infused over 4 hours (or longer, if clinically indicated). Patients must be monitored during the entire infusion, and for at least 2 hours after each infusion. Patients receiving the drug will receive specific monthly blood tests to detect and manage potentially serious risks associated with the drug, including immune thrombocytopenic purpura (ITP) and nephropathies, for four years after the last treatment.

The recommended first treatment course is 12mg/day for 5 consecutive days. The recommended second treatment course is 12 mg/day for 3 consecutive days administered 12 months after the initial treatment course. Lemtrada is supplied in single use, 2 ml glass vials. Each 2 ml vial is filled to deliver 1.2 ml of 10mg/ml solution (12mg) of Lemtrada. Patients should be pre-medicated with high dose corticosterioids (1,000 mg methylprednisolone or equivalent) immediately prior to Lemtrada infusion and for the first 3 days of each treatment course.

According to the requester, no existing code category adequately describes Lemtrada for use in treating patients with MS.

Preliminary Decision:

Discontinue existing code J9010 "Injection, Alemtuzumab, 10 mg"; and

Establish JXXXX Injection, Alemtuzumab, 1mg

HCPCS Public Meeting Agenda Item #5

May 8, 2015

Attachment# 15.018

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify AKYNZEO (netupitant and palonosetron) capsules. Applicant's suggested language: JXXXX - netupitant and palonosetron, oral, 300 mg/0.5 mg.

Background/Discussion:

Eisai Inc. submitted a request to establish a HCPCS code to identify Akynzeo. According to the requester, Akynzeo is a fixed combination of netupitant, a substance P/neurokinin 1 (NK1) receptor antagonist, and palonosetron, a seratonin-3 (5-HT3) receptor antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with cancer chemotherapy, including but not limited to, highly emotogenic chemotherapy. Oral palanosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.

Cancer chemotherapy is associated with nausea and vomiting, particularly when agents, such as cisplatin, are used. 5-HT3 receptors are located on the vagal nerve terminals the periphery and centrally in the chemoreceptor trigger zone of the area postrema. Chemotherapy agents produce nausea and vomiting by stimulating the release of serotonin from the enterochromaffin cells of the small intestine. Seratonin activates 5-HT3 receptors located on vagal afferents to initiate the vomiting reflex. Development of acute emesis depends on seratonin and its 5-HT3 receptors have been demonstrated to selectively stimulate the emetic response. Delayed emesis is associated with the activation of tachykinin family neurokinin 1 (NK1) receptors (broadly distributed in the central and peripheral nervous systems) by substance P. As shown in in vitro and in vivo studies, netupitant inhibits substance P mediated responses.

The typical dosage is one capsule (300 mg netupitant/0.5 mg palonosetron) by oral administration, 1 hour prior to the start of chemotherapy.

The requester comments that there is not an existing HCPCS code that identified netupitant and palonosetron for oral administration.

Preliminary Decision:

Establish Q9978 Netupitant 300 mg and Palonosetron 0.5 mg, effective 7/1/15;
Discontinue Q9978 12/31/15
Establish JXXXX effective 1/1/16 to replace discontinued Q code

HCPCS Public Meeting Agenda Item #6

May 8, 2015

Attachment# 15.019

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify Sylvant® (siltuximab). Applicant's suggested language: JXXXX - Injection, siltuximab, per 100 mg.

Background/Discussion:

Johnson & Johnson Healthcare Systems Inc. submitted a request for a HCPCS code to identify siltuximab. According to the requester, Sylvant is a human-mouse chimeric monoclonal antibody that binds human interleukin-6 (IL-6) and prevents the binding of IL-6 to both soluble and membrane-bound IL-6 receptors. IL-6 has been shown to be involved in induction of immunoglobulin secretion. Sylvant is indicated for the treatment of patients with Multicentric Castleman's Disease (MCD) who are human immunodeviciency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

Sylvant 11mg/kg is administered over 1 hour as an intravenous infusion administered every 3 weeks until treatment failure. Hematology laboratory tests should be performed prior to each dose for the first 12 months, and every 3 dosing cycles thereafter. If the following treatment criteria are not met: (absolute neutrophil count before first Sylvant administration is >=1.0 x 10^9/L, re-treatment criteria are >=1.0 x 10^9/L. Platelet count before first Sylvant administration is >=75 x 10^9/L, re-treatment criteria are >=50 x 10^9/L. Hemoglobin before first Sylvant administration is < 17 g/dL, re-treatment criteria are <17 g/dL), consider delaying treatment with Sylvant. Do not reduce dose. Sylvant should not be administered to patients with severe infections until the infection resolves. Sylvant should be discontinued in patients with severe infusion-related reactions, anaphylaxis, severe allergic reactions, or cytokine release syndromes.

Sylvant is supplied as a lyophilized powder in individually packaged 100 mg and 400 mg single-use vials. After reconstitution, the solution contains 20 mg/mL siltuximab for IV infusion.

According to the requester, there are no existing codes that describe siltuximab.

Preliminary Decision:

Establish JXXXX, Injection, Siltuximab, 10mg.

HCPCS Public Meeting Agenda Item #7

May 8, 2015

Attachment# 15.031

Topic/Issue:

Request to create a unique Level II HCPCS code to identify RAPIVAB™ (peramivir injection). Applicant's suggested language: JXXXX - Injection, peramivir, 200 mg

Background/Discussion:

On behalf of Biocryst Pharmaceutical, Inc., a request was submitted to establish a HCPCS code to identify Rapivab™ (peramivir). According to the requester, Rapivab is an influenza virus neuraminidase inhibitor indicated for the treatment of acute uncomplicated influenza in adult patients (18 years and older), *who have been symptomatic for no more than two days*. Rapivab injection is an isotonic solution supplied in 200 mg per 20 mL (10 mg per mL) vials. The recommended dose is a single 600 mg dose, administered within 2 days of onset of influenza symptoms, via intravenous infusion over 15 to 30 minutes. The recommended dose for patients with creatinine clearance 30-49 mL/min is 200 mg and the recommended dose for patients with creatinine clearance 10-29 mL/min is 100 mg. No dose adjustment is required for single administration in patients with creatinine clearance of 50 mL/min or higher.

According to the requester, there are no existing HCPCS codes that describe Rapivab.

Preliminary Decision:

Establish JXXXX, Injection, Peramivir, 1mg.

HCPCS Public Meeting Agenda Item #8

May 8, 2015

Attachment# 15.028

Topic/Issue:

Second request to establish a unique Level II HCPCS code to identify Recombinant C1 Esterase Inhibitor, Trade Name: RUCONEST. Applicant's suggested language: JXXXX - Injection, C-1 Esterase Inhibitor (Recombinant) [RUCONEST], per unit (1vial)

Background/Discussion:

On behalf of Santarus, Inc., a subsidiary of Salix Pharmaceuticals and licensee for North American commercialization of Ruconest, manufactured by Pharming 'group N.V., Netherlands, a request was submitted to establish a new HCPCS code to identify RUCONEST. According to the requester, Ruconest is a recombinant C1 esterase inhibitor indicated for the treatment of acute attacks of Hereditary Angiodema (HAE) symptoms (except laryngeal attacks). HAE is caused by a functional deficiency of the C1 esterase inhibitor protein present in the blood, which regulates the immune system. Deficiency of this protein can lead to attacks of swelling in the skin, abdomen, larynx, and other areas, resulting in pain, debilitation, difficulty breathing and other symptoms. Unlike Other C1 esterase inhibitors derived from human plasma, Ruconest is a recombinant analog of human C1 esterase inhibitor purified from the milk of transgenic rabbits.

Ruconest is dosed based on weight. The recommended dose is 50 IU per kg for persons weighing <84 kg; and a recommended maximum dose of 4200 IU for persons weighing >=84 kg. It is administered as a slow intravenous injection over approximately 5 minutes. In most cases, a single dose of Ruconest is sufficient to treat an acute angiodema attack. However, in case of insufficient clinical response, a second dose can be administered at the recommended dose level for the patient's body weight. No more than 2 doses should be administered in a 24-hour period.

Ruconest is supplied in cartons of one single-use vial containing 2100 IU lyophilized powder for reconstitution with 14 mL sterile water for injection (not supplied).

According to the requester, no existing HCPCS codes accurately describe Ruconest..

Preliminary Decision:

Establish JXXXX, Injection, C1 Esterase Inhibitor (Recombinant) Ruconest, 10 units.

HCPCS Public Meeting Agenda Item #9

May 8, 2015

Attachment# 15.035

Topic/Issue:

Request to establish a unique Level II HCPCS Code to identify (carbidopa and levodopa) enteral suspension, Trade Name: DUOPA™. Applicant's suggested language: JXXXX - DUOPA™ (carbidopa and levodopa enteral suspension 1:4 ratio), per 5 mg carbidopa and 20 mg levodopa

Background/Discussion:

On behalf of AbbieVie. Inc. an application was submitted to establish a HCPCS code to identify Duopa™, a carbidopa and levodopa enteral suspension. Duopa is a combination of carbidopa (an aromatic amino acid decarboxylation inhibitor) and levodopa (and aromatic amino acid) indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease who do not have adequate control with other Parkinson's disease medications.

The maximum recommended daily dose of Duopa is 2000 mg levodopa per day administered over 16 hours. Prior to initiating Duopa, convert patients from all forms of levodopa to oral immediate-release carbidopa-levodopa tablets (1:4 ratio). Titrate total daily dose based on clinical response for the individual patient. Administer Duopa into the jejunum through a percutaneous endoscopic gastrostomy with jejunal tube (PEG-J) with the CADD®-Legacy 1400 portable infusion pump. Total daily dose should be individually titrated to an optimal clinical response for the patient. DUOPA is supplied as an enteral suspension: 4.63 mg carbidopa and 20 mg levodopa per mL in a single-use cassette containing 100 mL of suspension.

According to the applicant, no exiting HCPCS identify DUOPA.

Preliminary Decision:

Establish JXXXX, Carbidopa 5 mg/Levodopa 20 mg Enteral Suspension.

HCPCS Public Meeting Agenda Item #10

May 8, 2015

Attachment# 15.036

Topic/Issue:

Request to establish a new Level II HCPCS code to identify sulfur hexafluoride, lipid-type-A microspheres injectable suspension, Trade Name: Lumason. Applicant's suggested language: QXXXX Injection, sulfur hexafluoride lipid microspheres, per ml

Background/Discussion:

Bracco Diagnostics, Inc. submitted a requests a new HCPCS code to identify Lumason (sulfur hexafluoride lipid-type-A microspheres). According to the requester, Lumason is an ultrasound contrast agent indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border. The recommended dose after reconstitution is 2mL administered as an intravenous bolus injection during echocardiography. During a single examination, a second dosage of 2mL may be injected to prolong contrast enhancement. Each injection should be followed with an intravenous flush using 5mL of .9% Sodium Chloride. Lumason is supplied in boxes containing 5 kits. Each kit includes: Lumason vial containing 25mg of lipid-type A lyophilized powder; a prefilled syringe containing 5 mL Sodium Chloride 0.9% injection; and Mini-Spike. Following reconstitution with 5 mL diluent, Lumason injectable suspension contains 1.5 to 5.6 x 10 (to the eighth power) microspheres/mL with 45 mcg/mL of sulfur hexafluoride.

According to the requester, no existing codes describe injection of sulfur hexafluoride lipid-type A microspheres.

Preliminary Decision:

Establish QXXXX, Injection, Sulfur Hexafluoride Lipid Microspheres, per ml.

HCPCS Public Meeting Agenda Item #11

May 8, 2015

Attachment# 15.020

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify ferric pyrophosphate citrex solution, Trade Name: TRIFERIC®. Applicant's suggested language: JXXXX - TRIFERIC® (ferric pyrophosphate citrex) solution; 5.44 mg of iron per ml.

Background/Discussion:

Rockwell Medical, Inc. submitted a request to establish a HCPCS code to identify Triferic® (ferric pyrophosphate citrex) solution, an iron-replacement product indicated for the replacement of iron for adult patients with chronic kidney disease who receive hemodialysis. According to the requester, Triferic-iron binds directly to transferrin for transport to erythroid precursors in the bone marrow and incorporation into hemoglobin. One ampule of Triferic is added to liquid 2.5 gallons bicarbonate concentrate before being used in the dialysis machine. Each ampule contains 27.2mg iron (III) per 5mL, (5.44 mg of iron (III) per mL. Single use ampules are available in 5 ampules per pouch. The requester claims a significant therapeutic distinction when Triferic is used, compared with other iron replacements, in that Triferic replaces iron loss with each dialysis, maintains hemoglobin concentrations, and reduces erythropoiesis –stimulating agent requirements while not increasing iron stores and avoiding the risks of iron overload.

According to the requester, there are currently no HCPCS codes that identify Triferic.

Preliminary Decision:

Establish Q9976 Injection, Ferric Pyrophosphate Citrate Solution, 0.01 mg of iron eff. 7/1/15.

Discontinue Q9976 on 12/31/15

Establish JXXXX Injection, Ferric Pyrophosphate Citrate Solution, 0.01 mg of iron

HCPCS Public Meeting Agenda Item #12

May 8, 2015

Attachment# 15.029

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify ceftolozane/tazobactam, ZERBAXA™. Applicant's suggested language: JXXXX Injection, ceftolozane/tazobactam, 1.5g.

Background/Discussion:

On behalf of Cubist Pharmaceuticals, a request was submitted to establish a HCPCS code to identify Zerbaxa™. Zerbaxa is a ceftolozane/tazobactam combination product consisting of cephalosporin-class antibacterial drug and a beta-lactamase inhibitor indicated for the treatment of complicated intra-abdominal infections and complicated urinary tract infections, including Pyelonephritis. ZERBAXA™ for injection 1.5 g (1 g/0.5g) every 8 hours by IV infusion administered over 1 hour for patients 18 years or older with creatinine clearance greater than 50 mL/min. Dosage is reduced in patients with impaired renal function. The duration of therapy should be guided by the severity and site of infection and the patient's clinical and bacteriological progress. ZERBAXA™ for injection is supplied as powder for reconstitution in single use vials; each 1.5 g vial contains 1 g ceftolozane (equivalent to 1.147 g of ceftolozane sulfate) and 0.5 g tazobactam (equivalent to 0.537 g of tazobactam sodium).

According to the applicant, there are no existing HCPCS codes that describe ZERBAXA™.

Preliminary Decision:

Establish JXXXX, Injection, Ceftolozane 50mg and Tazobactam 25mg.

HCPCS Public Meeting Agenda Item #13

May 8, 2015

Attachment# 15.030

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify tedizolid phosphate, Sivextro™. Applicant's suggested language: JXXXX - Injection, tedizolid phosphate, 200 mg

Background/Discussion:

On behalf of Cubist Pharmaceuticals, a request was submitted to establish a HCPCS code to identify Sivextro™ (tedizolid phosphate). According to the requester, Sivextro is an oxazolidinone-class antibacterial drug indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the certain Gram positive microorganisms. Recommended dosage is 200 mg administered once daily orally or as an intravenous infusion over 1 hour for six days. Sivextro is supplied as lyophilized powder for injection in single-use vials of 200 mg, in packages of ten 200 mg vials.

According to the applicant, no existing HCPCS codes to accurately describe Sivextro.

Preliminary Decision:

Establish JXXXX, Injection, Tedizolid Phosphate, 1mg.

HCPCS Public Meeting Agenda Item #14

May 8, 2015

Attachment# 15.034

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify Keytruda® (pembrolizumab). Applicant's suggested language: J9XXX - Injection, pembrolizumab, 1 mg.

Background/Discussion:

Merck & Co., Inc. submitted a request to establish a HCPCS code to identify Keytruda, a human programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. This indication is approved under accelerated approval based on tumor response rate and durability of response. An improvement in survival or disease-related symptoms has not yet been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. According to the applicant, many tumors evade the body's immune system using a mechanism that exploits the programmed death 1 (PD-1) inhibitory checkpoint protein. Keytruda is an anti-PD-1 antibody designed to help restore the ability of the immune system to recognize and target cancer cells by exerting dual ligand blockade of the PD-1 pathway.

The recommended dose of Keytruda is 2 mg/kg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.

Keytruda is currently supplied as a lyophilized powder in 50 mg single-use vials. Merck anticipates that before January 1, 2016, Keytruda will be supplied only as a liquid in a 100 mg single-use vial.

According to the requester, no existing code describes Keytruda for use in the physician's office.

Preliminary Decision:

Establish JXXXX, Injection, Pembrolizumab, 1mg.

HCPCS Public Meeting Agenda Item #15

May 8, 2015

Attachment# 15.046

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify OPDIVO® (nivolumab). Applicant's suggested language: J9XXX - Injection, nivolumab, 1 mg

Background/Discussion:

Bristol-Myers Squibb Company submitted a request. Opdivo is a human programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

The recommended dose of Opdivo is 3 mg/kg administered as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity. Opdivo is supplied in cartons containing either one 40 mg/4 mL single-use vial or one 100 mg/10 mL single-use vial.

According to the requester, no existing codes describe Opdivo.

Preliminary Decision:

Establish JXXXX, Injection, Nivolumab, 1mg.

HCPCS Public Meeting Agenda Item #16

May 8, 2015

Attachment# 15.038

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify Signifor® (LAR), (pasireotide). Applicant's suggested language: JXXXX- injection, pasireotide long acting, 1 mg

Background/Discussion:

Novartis Pharmaceuticals Corporation submitted a request to establish a HCPCS code to identify Signifor® LAR (pasireotide), for injectable suspension. Signifor LAR is a somatostatin analog indicated for the treatment of adult patients with acromegaly who have had inadequate response to surgery and/or for whom surgery is not an option. According to the requester, Pasireotide binds to somatostatin receptors (SSTRs). The recommended initial dose of Signifor LAR is 40 mg administered by intramuscular injection once every 4 weeks. Adjust dose based on biochemical response and tolerability. Evaluate fasting plasma glucose, hemoglobin A1c, liver enzyme tests, electrocardiogram, serum magnesium and serum potassium prior to starting. Optimize glucose control in patients with poorly controlled diabetes mellitus prior to starting. The recommended initial dose for patients with moderate hepatic impairment for Child Pugh B is 20 mg every 4 weeks (maximum dose is 40 mg every 4 weeks); avoid use of this product for Child Pugh C. Signifor LAR for injectable suspension is supplied in single-use kits. Each kit contains 20, 40, or 60 mg powder in a vial to be reconstituted with the provided 2 mL diluent; one pre-filled syringe containing 2 mL diluent; one vial adapter for reconstitution; and one 20G x 1.5 safety injection needle.

According to the requester, no HCPCS code describes pasireotide.

Preliminary Decision:

Establish JXXXX, Injection Pasireotide long acting, 1mg.

HCPCS Public Meeting Agenda Item #17

May 8, 2015

Attachment# 15.041

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify DALVANCE (dalbavancin). Applicant's suggested language: JXXXX - Injection, dalbavancin, 10 mg.

Background/Discussion:

Durata Therapeutics, an affiliate of Actavis, submitted a request to establish a HCPCS code to identify Dalvance (dalbavancin), for injection. Dalvance is indicated for the treatment of acute bacterial skin and skin structure infection (ABSSSI) caused by designated susceptible strains of Gram-positive microorganisms. According to the requester, Dalvance binds to the C-terminal l-lysyl-d-alanyl-d-alanine subunit of peptidoglycan precursors, inhibiting cross-linking and polymerization in bacterial cell walls, interrupting cell wall synthesis, and causing apoptosis of bacterial cells.

A two-dose regimen is recommended: 1000 mg administered by intravenous infusion over 30 minutes, followed one week later by 500 mg. Dosage adjustment for patients with creatinine clearance less than 30 mL/minute and not receiving regularly scheduled hemodialysis is 750 mg followed one week later by 375 mg. Dalvance is supplied as in individually cartooned single-use vials containing a dose of 500 mg of anhydrous dalbavancin as a powder.

According to the requester, a new code is warranted for Dalvance because it is the only drug with the active ingredient dalbavancin that has been approved by the FDA, and no existing code describes it.

Preliminary Decision:

Establish JXXXX, Injection, Dalbavancin, 5mg.

HCPCS Public Meeting Agenda Item #18

May 8, 2015

Attachment# 15.032

Topic/Issue:

Request to revise the descriptor of existing code J7302 to add brand name and duration of use. Applicant's suggested language: Revise existing code J7302 which currently reads: "Levonorgestrel- releasing intrauterine contraceptive system, 52 mg"; to instead read: "Levonorgestrel- releasing intrauterine contraceptive system (Mirena), 52 mg, five years duration of use".

Background/Discussion:

Bayer Healthcare Pharmaceuticals, Inc, manufacturer of Mirena, submitted a request to revise existing HCPCS J7302 "LEVONORGESTREL-RELEASING INTRAUTERINE CONTRACEPTIVE SYSTEM, 52mg" to include the product brand name and duration use. According to the requester, Mirena® is an intrauterine contraceptive indicated to prevent pregnancy and for the treatment of heavy menstrual bleeding for women who choose to use an estrogen/progesterone intrauterine device as their method of contraception. Mirena contains 52 mg of Levonorgestrel released at a progressively decreasing rate over a five- year period.

According to the requester, the suggested code descriptor revision is necessary in order to facilitate appropriate billing by providers, and claims processing by state Medicaid agencies and private payers for Mirena. The addition of the brand name and duration of use to the "Mirena code" descriptor would allow for clarity between the current "Skyla and Mirena codes". While Skyla and Mirena are similar products, they differ significantly in indication, duration of use, and dosage, therefore the additional coding "precision" is needed.

Preliminary Decision:

Existing code J7302 "Levonorgestrel-releasing intrauterine contraceptive system, 52mg", adequately describes the product that is the subject of this request.

HCPCS Public Meeting Agenda Item #19

May 8, 2015

Attachment# 15.009

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a new drug, Iluvien®, (fluocinolone acetonide intravitreal implant 0.19 mg). Applicant's suggested language: JXXXX-injection, fluocinolone acetonide, ILUVIEN, intravitreal implant, 0.19 mg.

Background/Discussion:

Alimera Sciences submitted a request to establish a new HCPCS code to identify Iluvien®. According to the requester, Iluvien is a sterile non-biodegradable intravitreal implant containing 0.19 mg of fluocinolone acetonide in a drug delivery system designed to release fluocinolone acetonide at an initial rate of 0.25 micrograms/day and lasting 36 months. Iluvien is recommended for ophthalmic intravitreal injection. The optimal placement of the implant is inferior to the optic disc and posterior to the equator of the eye. Iluvien contains a corticosteroid and is indicated for the treatment of diabetic macular edema in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. Iluvien inhibits the inflammatory response to a variety of inciting agents: edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation.

Iluvien is supplied in a sterile single use preloaded applicator with a 25-gauge needle, packaged in a tray sealed with a lid inside a carton.

According to the requester, no existing codes describe the Iluvien implant dosage or formulation for use in the physician office setting.

Preliminary Decision:

Establish JXXXX Injection, fluocinolone acetonide, intravitreal implant, 0.01mg.

HCPCS Public Meeting Agenda Item #20

May 8, 2015

Attachment# 15.010

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify Entyvio® (vedolizumab).
Applicant's suggested language: JXXXX - injection, vedolizumab, 1 mg.

Background/Discussion:

Takeda Pharmaceuticals America, Inc. submitted a request to establish a HCPCS code to identify vedolizumab, an integrin receptor antagonist indicated for use in treating adult patients with moderate to severely active Ulcerative Colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrat3ed dependence on corticosteroids: inducing and maintaining clinical response or clinical remissions; improving endoscopic appearance of the mucosa; or achieving corticosteroid-free remission. It is also indicated for treatment of adult patients with moderately to severely active Crohn's Disease (CD) who have had inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids: achieving clinical response, clinical remission, or corticosteroid-free remission. According to the requester, vedolizumab is a novel a4ß7 integrin antagonist that inhibits lymphocyte trafficking to the gastrointestinal tract. It binds the a4ß7 integrin and blocks its interaction with mucosal addressin cell adhesion molecule 1 (MAdCAM-1) thereby inhibiting the migration of memory T lymphocytes across the endothelium into inflamed gastrointestinal parenchymal tissue.

The recommended dosage in UC and CD is 300 mg infused intravenously over approximately 30 minutes at zero, two and six weeks, then every eight weeks thereafter. Vedolizumab is supplied as300 mg lyophilized vedolizumab in a single-use 20 mL vial.

According to the requester, no existing HCPCS code identifies vedolizumab.

Preliminary Decision:

Establish JXXXX Injection, Vedolizumab, 1mg.

HCPCS Public Meeting Agenda Item #21

May 8, 2015

Attachment# 15.012

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify a new sodium hyaluronate for injection, Gel-Syn™. Applicant's suggested language: J732XX - Hyaluronan or Derivative, Gel-Syn, For Intra-Articular Injection, Per Dose.

Background/Discussion:

On behalf of Institut Biochimique SA (IBSA) Farmaceutici Italia Srl, a request was submitted to establish a HCPCS code to identify Gel-Syn, a product containing sodium hyaluronate, a viscoelastic material made from bacterial fermentation indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen). According to the requester, Gel-Syn is a sterile buffered solution of 16.8 mg/2.0 ml (0.84%) highly purified, chemically unmodified sodium hyaluronate with a molecular weight of approximately 1100 kDa. Gel-Syn should only be injected into the synovial space. The injected sodium hyaluronate lubricates the osteoarthritic knee to enhance viscoelasticity, thereby augmenting the knee's natural shock absorbing capability and promoting pain relief.

Gel-Syn is supplied in a sterile disposable 2.25 mL syringe containing 2.1 mL of solution. The content of the syringe is injected directly into the knee, with 2.0 mL being delivered. Each 1 mL Gel-Syn contains 8.4 mg Sodium Hyaluronate. The syringe is sealed within a polyvinyl chloride blister pack. Depending on the packaging configuration, one or three blister(s) is/are contained within a single cardboard carton box.

According to the requester, no existing HCPCS codes adequately describe Gel-Syn.

Preliminary Decision:

Establish JXXXX, Hyaluronan or Derivative, Gel-Syn, for Intra-articular Injection, 0.1mg.

HCPCS Public Meeting Agenda Item #22

May 8, 2015

Attachment# 15.016

Topic/Issue:

Request to establish another Level II HCPCS code to identify Orbactiv™ (oritavancin). Applicant's suggested language: JXXXX - Injection, oritavancin, 10 mg. This descriptor is consistent with the C-code recently issued for Orbactiv, C9444, Injection, oritavancin, 10 mg.

Background/Discussion:

The Medicines Company submitted a request to establish another HCPCS code to identify Orbactiv, a lipoglycopeptide antibacterial drug indicated for the treatment of adults with acute bacterial skin and skin structure infections caused or suspected to be caused by susceptible isolates of designated Gram-positive microorganisms. According to the requester, Obactiv confers antibacterial activity against Gram-positive bacteria via inhibition of bacterial cell wall synthesis in Gram-positive pathogens by preventing transglycosylation; perturbation of bacterial membrane integrity in both exponential and stationary periods of growth; and enhanced interactions with cell wall bridging segments, leading to inhibition of transpeptidation.

The recommended dose is 1200 mg administered by intravenous infusion over three hours. Orbactiv is supplied as a single 5 mL vial containing lyophilized powder equivalent to 400 mg of oritavancin. Three vials are packaged in a carton to supply a single 1200 mg dose treatment.

According to the applicant, while existing code C9444 Injection, oritavancin, 10 mg is available, there is no existing HCPCS code to identify Orbactiv used in the physician's office.

Preliminary Decision:

Establish JXXXX, Injection, Oritavancin, 10mg.

HCPCS Public Meeting Agenda Item #23

May 8, 2015

Attachment# 15.015

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a renal replacement solution, Trade name: Phoxillum. Applicant's suggested language: "JXXXX Renal Replacement Solution (Phoxillum), 5000 ml"

Background/Discussion:

Baxter Healthcare Corporation submitted a request to establish a new Level II HCPCS code to identify Phoxillum. According to the requester, Phoxillum is a bicarbonate-buffered replacement fluid and dialysate "renal replacement solution". Phoxillum is indicated for Continuous Renal Replacement Therapy (CRRT), a standard therapy used to treat acute renal failure. Replacement solutions are provided to replace plasma volume removed by ultrafiltration and to correct electrolyte and acid-base imbalances. It may also be used in cases of drug poisoning when CRRT is used to remove dialyzable substances.

Phoxillum is supplied in two strengths: BK4/2.5 and B22K4/0; in a two-compartment bag with a small and a large compartment, containing buffer solutions. The two solutions must be mixed immediately prior to use. The solution is administered via excorporeal dialysis equipment appropriate for CRRT, and should only be administered under the direction of a physician competent in intensive care treatment including CRRT.

The applicant states that a new code is warranted based on the unique nature of Phoxillum.

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 PHOXILLUM, which is included in the DRG.

HCPCS Public Meeting Agenda Item #24

May 8, 2015

Attachment# 15.013

Topic/Issue:

Request to establish a Level II HCPCS code to identify immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase, HYQVIA™, for subcutaneous administration only. Applicant's suggested language: JXXXX - Injection, Immune Globulin, (HYQVIA), 100 mg.

Background/Discussion:

Baxter Healthcare Corporation submitted a request to establish a HCPCS code to identify Immune Globuline Infusion 10% (Human), Hyqvia™, an immune globulin with a recombinant human hyaluronidase, indicated for the treatment of Primary Immunodeficiency (PI) in adults. According to the requester, Hyqvia increases dispersion and absorption of the Immune Globulin Infusion 10% (Human). The immune Globulin Infusion supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial and viral agents, and contains a spectrum of antibodies capable of interacting with and altering the activity of cells of the immune system as well as antibodies capable of reacting with cells such as erythrocytes. The Recombinant Human Hyaluronidase of HYQVIA increases permeability of the subcutaneous tissue by temporarily depolymerizing hyaluronan. In the doses administered, Recombinant Human Hyaluronidase of HYQVIA acts locally.

Hyqvia may be administered by a healthcare professional, caregiver or self-administered by the patient after appropriate training. The following dosages below are for *subcutaneous infusion* only. Initial treatment interval/dosage ramp-up schedule and infusion rate varies based on the subject's weight. Week one (1st infusion) 1 -week dose is 7.5 grams. Week 2 (2nd infusion) 2-week dose is 15 grams. Week 3, no infusion. Week 4 (3rd infusion) 3-week dose is 22.5 grams. Week 5 and 6, no infusion. Week 7 (4th infusion, if required) 4-week dose is 30 grams. The two components of HYQVIA must be used sequentially.

HYQVIA is supplied in a dual vial unit of 2 single-use vials containing 10% IgG and Recombinant Human Hyaluronidase, available in strengths, expressed as Immune Globulin 10% Grams Protein: Recombinant Human Hyaluronidase Units 2.5:200 (25 mL); 5:400 (50 mL); 10:800 (100 mL): 20:1600 (200 mL); and 30:2400 (300 mL).

According to the requester, there is no existing HCPCS code to identify Hyqvia.

Preliminary Decision:

Establish JXXXX, Injection, Immune Globulin/Hyaluronidase, (Hyqvia), 100mg Immuneglobulin.

HCPCS Public Meeting Agenda Item #25

May 8, 2015

Attachment# 15.014

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify Antihemophilic Factor (Recombinant), Porcine Sequence, Obizur™. Applicant's suggested language: JXXXX - Injection, Factor VIII (Antihemophilic Factor, Recombinant, Porcine Sequence), (Obizur), Per IU.

Background/Discussion:

Baxter Healthcare Corporation submitted a request to establish a HCPCS code to identify Antihemophilic Factor (recombinant), porcine sequence, an antihemophilic factor indicated for the treatment of bleeding episodes in adults with acquired hemophilia A. According to the requester, Obizur replaces the inhibited human factor VIII with a recombinant porcine sequence factor VIII based on the rationale that it is less susceptible to inactivation by circulating human factor VIII antibodies. Safety and efficacy of Obizur has not been established in patients with a baseline anti-porcine factor VIII inhibitor titer of greater than 20 BU. Obizur is not indicated for the treatment of congenital hemophilia A or von Willebrand disease.

Dose, frequency, and duration of treatment with OBIZUR depend on the location and severity of bleeding episode, target factor VIII levels, and the patent's clinical condition. Replacement therapy should be monitored in cases of major surgery or life-threatening bleeding episodes. Patients may vary in their pharmacokinetic (half-life, in vivo recovery) and clinical responses..

For intravenous use after reconstitution only, initial dose is 200 mg per kg., at a rate of 1 to 2 mL per minute. Titrate dose and frequency based on factor VIII recovery levels and individual clinical response. Obizur is available as a lyophilized powder in single-use vials containing nominally 500 units per vial. It is available in 1, 2, and 10 vial kits.

According to the applicant, there are no existing HCPCS codes that describe Obizur.

Preliminary Decision:

Establish JXXXX, Injection, Factor VIII (Antihemophilic Factor, Recombinant), (Obizur), per i.u.

HCPCS Public Meeting Agenda Item #26

May 8, 2015

Attachment# 15.001

Topic/Issue:

Request to establish a new level II HCPCS code to describe Fc fusion protein antihemophilic recombinant Factor VIII, brand name, Eloctate™. Applicant's suggested language: JXXXX Injection, Factor VIII (Antihemophilic Factor, Recombinant, Fc Fusion) (Eloctate™), Per IU

Background/Discussion:

Biogen Idec, Inc. submitted a request to establish a HCPCS code to identify Eloctate™, an antihemophilic Factor (Recombinant), Fc Fusion Protein indicated in adults and children with Hemophilia A (congenital Factor VIII deficiency) for control and prevention of bleeding episodes, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Eloctate temporarily replaces missing clotting Factor VIII needed for effective hemostasis in Hemophilia A patients.

Eloctate is administered by intravenous infusion and is supplied as a lyophilized powder for reconstitution in single-use vials containing nominally 250, 500, 750, 1000, 1500, 2000 or 3000 IUs of Factor VIII potency. Dosage is one unit per kg body weight to raise the Factor VIII level by 2 percent IU/dL. Dosing for routine prophylaxis is: 50 IU every 4 days; may be adjusted based on patient response with dosing in the range of 25-65 IU/kg at 3 – 5 day intervals. More frequent or higher doses up to 80IU/kg may be required in children less than 6 years of age. Dosing formulate for bleedinge0pisodes and perioperative management: Estimated Increment of Factor Viii (IU/dL or % of normal) = [Total dose (IU)/kg] x 2 (IU/dL per IU/kg OR Required Dose (IU) = kg x desired Factor VIII rise (IU/dLor % of normal) x 0.5 (IU/kg per IU/dL).

Preliminary Decision:

1. Establish Q9975 Injection, Factor VIII Fc Fusion (Recombinant), Per IU, effective 4/1/15

2. Discontinue Q9975, Effective 12/131/15

3. Establish JXXXX Injection, Factor VIII Fc Fusion (Recombinant), Per IU, Effective 1/1/16

HCPCS Public Meeting Agenda Item #27

May 8, 2015

Attachment# 15.027

Topic/Issue:

Third request to establish a unique Level II HCPCS code to identify injectable Epoprostenol Sodium, Velitri®. Applicant's suggested language: JXXXX Injection, Epoprostenol, Saline Diluent, Velitri, 0.5 mg

Background/Discussion:

Actelion submitted a third request to establish a unique code to identify Veletri®, a prostanoid vasodilator indicated for treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases. According to the requester, Veletri's active ingredient is prostenol (PG12, PGX, prostacyclin) a metabolite of arachidonic acid (a naturally occurring prostaglandin with potent vasodilatory activity and inhibitory activity of platelet aggregation). Epoprostenol has two major pharmacological actions; direct vasodilation of pulmonary and systemic arterial vascular beds and inhibition of platelet aggregation.

Veletri is administered by continuous intravenous infusion via a central venous catheter using an ambulatory infusion pump. Temporary peripheral intravenous infusion may be used until central access is established. Chronic infusion should be initiated at 2 ng/kg/min and increased in increments of 2ng/kg/min every 15 minutes or longer, until a tolerance limit to the drug is established or further increases in the infusion rate are not clinically warranted. If dose limiting pharmacologic effects occur, then the infusion rate should be decreased until Veletri is tolerated.

Veletri is packaged in 1-vial cartons of 10 mL vials containing lyophilized epoprostenol sodium 0.5 mg (500,000 ng) or 1.5 mg (1,500,000 ng).

The requester comments that, while Veletri is currently coded at J1325 "Injection, epoprostenol, 0.5 mg", Veletri is not adequately described by this code because it is not therapeutically equivalent to other epoprostenol formulations and differs significantly in stability.

Preliminary Decision:

In accordance with the definition of therapeutic equivalence in section 1847A(c)(6)(C)(i)(I) and 1847A(c)(6)(F)(i) of the Social Security Act, Veletri meets the definition of a multi-source drug. As such, existing code J1325 "Injection, Epoprostenol, 0.5mg" adequately describes Veletri.

HCPCS Public Meeting Agenda Item #28

May 8, 2015

Attachment# 15.039

Topic/Issue:

Request to establish a unique Level II HCPCS code to identify Cresemba (isavuconazonium) for intravenous infusion. Applicant's suggested language: isavuconazonium, intraveneous, per 1 mg.

Background/Discussion:

Astellas Pharma US, Inc. submitted a request to establish a HCPCS code to identify Cresemba (isavuconazonium) for intravenous infusion. Isavuconazonium sulfate, the active ingredient in Cresemba, is a novel, water-soluble broad spectrum antifungal agent developed for the treatment of adults with invasive aspergillosis and invasive mucormycosis. Following IV administration, isavuconazonium is rapidly converted by plasma esterases to the active moiety isavuconazole.

Cresemba is supplied in 2 formulations: an IV solution and an oral capsule. The IV formula is lyophilized powder containing 372.6 mg isaviconazonium sulfate (equivalent to 200 mg isavuconazole. Capsules contain 186 mg isavuconazonium sulfate (equivalent to 100 mg ofisavuconazone). Loading dose is 372 mg every 8 hours for 6 doses (48 hours) via oral (2 capsules) or IV administration (1 reconstituted vial). Maintenance dose is 372 mg once daily via oral (2 capsules) or IV administration (1 reconstituted vial) starting 12 to 24 hours after the last loading dose.

According to the applicant, there are no existing HCPCS codes that identify Cresemba.

Preliminary Decision:

Establish JXXXX Injection, Isavuconazonium, 1mg

HCPCS Public Meeting Agenda Item #29

May 8, 2015

Attachment# 15.017

Topic/Issue:

Request to establish a Level II HCPCS code to identify Avycaz™ (Ceftazidime-Avibactam). Applicant's suggested language: JXXXX - Injection, Ceftazidime-Avibactam, 2g/500mg.

Background/Discussion:

Actavis, Inc. submitted a request to establish a new HCPCS code to identify Avycaz™ (Ceftazidime-Avibactam) for injection, for intravenous use. Ceftazidime-Avibactam is a combination of a cephalosporin and a beta-lactamase inhibitor indicated for the treatment of patients 18 years or older with the following infections caused by designated susceptible microorganisms: complicated Intra-abdominal infections (cIAI), used in combination with metronidazole; and complicated urinary tract infections (cUTI), including Pyelonephritis. Avycaz is reserved for use in patients who have limited or no alternative treatment options.

Recommended dosage and frequency varies based on Creatinine Clearance level (mL/min): 2.5 grams (2 grams/0.5 grams) every 8 hours for CrCL over 50; 1.25 grams (1 gram/0.25 grams) every 8 hours for CrCL 31-50; 0.94 grams (0.75 grams/0.19 grams) every 12 hours for CrCL 16-30; 0.94 grams (0.75 grams/0.19 grams) every 24 hours for CrCL 6-15; and 0.94 grams (0.75 grams/0.19 grams) every 48 hours for CrCL of 5 or less. Avycaz for injection is supplied in single-use vials containing 2 grams ceftazidime and 0.5 grams avibactam, lyophilized powder.

The requester claims that use of Ceftazidime-Avibactam confers a significant therapeutic distinction compared with. It represents a substantial clinical improvement in the treatment of patients diagnosed with cIAI or cUTI that are known or suspected to be caused by Gram-negative bacteria resistant to penicillin, cephalosporin, and/or carbapenem antibiotics. There is no existing HCPCS code that describes Ceftazidime in combination with Avibactam.

Preliminary Decision:

Establish JXXXX Injection, Ceftazidime and Avibactam 0.5g/0.125g