

**Centers for Medicare & Medicaid Services (CMS)
Level II Healthcare Common Procedure Coding System (HCPCS)
Application Summary, 2015 – 2016 Coding Cycle, for Items Discussed at the
Drugs, Biologicals, and Radiopharmaceuticals HCPCS Public Meeting
Friday, May 8, 2015**

Introduction and Overview

Approximately 75 people attended. The agenda included 29 items.

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

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

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

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

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

In November, all requestors will be notified in writing of the final decision regarding the HCPCS code modification request(s) they submitted. At about the same time, the HCPCS Annual Update is published at: www.cms.gov/HCPCSReleaseCodeSets/ANHCPCS/itemdetail.asp.

The latest information on the process for developing agendas and speaker lists for the public meetings, as well as the Guidelines for Proceedings at these CMS' Public Meetings, can be

found on the CMS HCPCS web site, specifically at: http://cms.gov/medhcpcsgeninfo/08_HCPCSPublicMeetings.asp#TopOfPage. In addition, the standard application format for requesting a modification to the HCPCS Level II Code Set, along with instructions for completion and background information regarding the HCPCS Level II coding process is available at: http://cms.gov/medhcpcsgeninfo/01_overview.asp#TopOfPage. The application form is updated annually and posted on the CMS HCPCS website sometime in the summer. A decision tree, outlining CMS' decision-making criteria is also available at: <http://cms.gov/medhcpcsgeninfo/downloads/decisiontree.pdf>.

**Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Agenda
for Drugs, Biologicals and Radiopharmaceuticals
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.

No Primary Speaker

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.

Primary Speaker: Yola Gawlik of Amgen, Inc.

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"

No Primary Speaker

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).

No Primary Speaker

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.

Primary Speaker: Stephen McMillan of Eisai, Inc.

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.

No Primary Speaker

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

No Primary Speaker

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 (1 vial)

Primary Speaker: Faith Dobson of Pharmaceuticals, Ltd.

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

Primary Speaker: Paul Radensky of McDermott Will & Emery

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

No Primary Speaker

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.

Primary Speaker: Dr. Raymond Pratt of Rockwell Medical

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.

No Primary Speaker

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

No Primary Speaker

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.

No Primary Speaker

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

No Primary Speaker

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

No Primary Speaker

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.

No Primary Speaker

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".

Primary Speaker: Kevin O’Leary of Bayer Healthcare

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.

No Primary Speaker

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.

No Primary Speaker

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.

No Primary Speaker

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.

Primary Speaker: Mike McGuire of The Medicines Company

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"

No Primary Speaker

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.

No Primary Speaker

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.

No Primary Speaker

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

No Primary Speaker

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

Primary Speaker: Michael Flinn of Actelion Pharmaceuticals

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, intravenous, per 1 mg.

No Primary Speaker

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.

No Primary Speaker

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/m² 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

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

Establish code J9032: 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.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with the CMS' preliminary decision, stating that C9449 is not a viable alternative to a permanent J- code because C codes cannot be used by all providers/suppliers of BLINCYTO; and continued use of not otherwise classified J-codes for BLINCYTO increases burden of providers and payers for claims processing and results in a missed opportunity for data collection. According to the speaker, not issuing a J code appears inconsistent with permanent J code decisions for other drugs.

Final Decision:

The CMS HCPCS Workgroup reconvened to consider all input provided and revised its decision. The following modification has been made to the HCPCS Level II standard, national code set:

Establish code J9039: Injection, blinatumonab, 1 microgram

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 intravenous 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

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

Establish code J9308: 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 healthcare 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 corticosteroids (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

Summary of Primary Speaker Comments at the Public Meeting:

Written comments were provided before the CMS' HCPCS Public Meeting in reaction to our preliminary decision supporting establishment of a permanent J code and also requested sooner coding.

Final Decision:

The CMS HCPCS Workgroup reconvened to this application together with all input provided. CMS upheld its decision. The following modifications have been made to the HCPCS Level II standard, national code set:

Discontinue code J9010, “Injection, Alemtuzumab, 10 mg”; Effective 12/31/15

Establish code Q9979, “Injection Alemtuzumab, 1mg”; effective 10/1/15

Discontinue code Q9979, “Injection Alemtuzumab, 1mg”; effective 12/31/15; and

Establish code J0202, “Injection, Alemtuzumab, 1mg”; effective 1/1/16

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 serotonin-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 emetogenic chemotherapy. Oral palonosetron 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. Serotonin activates 5-HT3 receptors located on vagal afferents to initiate the vomiting reflex. Development of acute emesis depends on serotonin 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 code Q9978

Summary of Primary Speaker Comments at the Public Meeting:

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

Final Decision:

The CMS HCPCS Workgroup reconvened to consider all input provided and upheld its decision. The following modifications have been made to the HCPCS Level II standard, national code set:

Establish code Q9978 Netupitant 300 mg and Palonosetron 0.5 mg, effective 7/1/15;

Discontinue code Q9978 12/31/15

Establish code J8655 "Netupitant 300 mg and Palonosetron 0.5 mg", effective 1/1/16, to replace discontinued code Q9978

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 immunodeficiency 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 $\geq 1.0 \times 10^9/L$, re-treatment criteria are $\geq 1.0 \times 10^9/L$. Platelet count before first Sylvant administration is $\geq 75 \times 10^9/L$, re-treatment criteria are $\geq 50 \times 10^9/L$. Hemoglobin before first Sylvant administration is $< 17 \text{ g/dL}$, re-treatment criteria are $< 17 \text{ g/dL}$), 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.

Summary of Primary Speaker Comments at the Public Meeting:

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

Final Decision: Establish code J2860: 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.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

CMS upheld its decision. We are pleased to inform you that the following modifications have been made to the HCPCS Level II standard, national code set:

Establish code J2547, Injection, Peramivir, 1mg.

HCPCS Public Meeting Agenda Item #8

May 8, 2015

Attachment# 15.028

Topic/Issue: Second request to establish a 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.

Summary of Primary Speaker Comments at the Public Meeting:

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

Final Decision:

Establish code J0596: Injection, C-1 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 existing HCPCS identify DUOPA.

Preliminary Decision:

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

Summary of Primary Speaker Comments at the Public Meeting:

The applicant agreed with CMS' preliminary decision to establish a new code, and provided a brief overview how the descriptor would translate into units of service.

Final Decision:

Establish code J7340: 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.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant provided a written comment that agreed with CMS' preliminary HCPCS coding decision.

Final Decision:

Establish code Q9950: 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

Summary of Primary Speaker Comments at the Public Meeting:

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

Final Decision:

Est. Q9976 "Injection, Ferric Pyrophosphate Citrate Solution, 0.1 mg of iron", 7/1/15

Discontinue code Q9976, Effective 12/31/15

Establish J1443 Injection, Ferric Pyrophosphate Citrate Solution, 0.1 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.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

Establish code J0695: 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.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

Establish cod J3090: Injection, Tedizolid Phosphate, 1mg.

HPCPS 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.

Summary of Primary Speaker Comments at the Public Meeting:

The applicant provided a written comment that agreed with CMS' preliminary decision.

Final Decision:

Establish code: J9271, 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.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

Establish J9299: 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.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

Establish code J2502: 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.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker offered comments at CMS' HCPCS Public Meeting in agreement with our preliminary decision.

Final Decision:

Establish code J0875: Injection, Dalbavancin, 5mg.

HPCPS 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.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision not to revise descriptor J7302. According to the speaker, recent FDA approval of another Levonorgestrel-releasing 52 mg IUD with a different duration use has created an urgent need for more specific HCPCS codes to distinguish among these products in order to facilitate appropriate patient treatment; avoid provider billing and coding errors; reduce cost to the Medicare program; and ensure accurate Medicaid rebate calculation and payments. The speaker requested that CMS assign a temporary Q code to the new product, in addition to revising J7302.

Final Decision:

The CMS HCPCS Workgroup reconvened to reconsider this application together with all input provided and revised its decision. The following modifications have been made to the HCPCS Level II standard, national code set:

1. Discontinue code J7302 "Levonorgestrel-releasing intrauterine contraceptive system, 52mg"; effective 12/31/15
2. Establish code J7297 "Levonorgestrel-releasing intrauterine contraceptive system, 52mg, 3 year duration"; effective 1/1/16
3. Establish code J7298 "Levonorgestrel-releasing intrauterine contraceptive system, 52mg 5 year duration"; effective 1/1/16

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.

Summary of Primary Speaker Comments at the Public Meeting:

There were no comments offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

Final Decision:

Establish code J7313: 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 demonstrated 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 $\alpha 4\beta 7$ integrin antagonist that inhibits lymphocyte trafficking to the gastrointestinal tract. It binds the $\alpha 4\beta 7$ 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 as 300 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.

Summary of Primary Speaker Comments at the Public Meeting:

There were no comments offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

Final Decision: Establish code: J3380 Injection, Vedolizumab, 1mg.

HPCPS 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.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker offered comments at CMS' HCPCS Public Meeting in agreement with our preliminary decision.

Final Decision:

Establish code J7328: 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, Orbactiv 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.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker agreed with CMS' preliminary decision.

Final Decision:

Establish code J2407: 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 extracorporeal 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.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

CMS upheld its decision. This request to establish a Level II HCPCS code to identify Phoxillum has not been approved. Phoxillum, when used, 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 Immune globulin.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

Establish code J1575: Injection, Immune Globulin/Hyaluronidase, (Hyqvia), 100mg
Immunoglobulin

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 patient'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.

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision: Establish code J7188: 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 bleeding episodes 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

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

CMS upheld its decision. We are pleased to inform you that the following modifications have been made to the HCPCS Level II standard, national code set:

1. Establish code Q9975: “Injection, Factor VIII, Fc Fusion Protein (Recombinant), Per IU”; Effective 4/1/15
2. Discontinue code Q9975; Effective 12/31/15
3. Establish code J7205: “Injection, Factor VIII, Fc Fusion Protein (Recombinant), Per IU”; Effective 1/1/16

HPCPS 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, Veletri®. Applicant's suggested language: JXXXX Injection, Epoprostenol, Saline Diluent, Veletri, 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.

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker disagreed with CMS' preliminary decision, stating that Veletri is not a multi-source drug since it has no therapeutic equivalents in the FDA Orange Book. In addition, Veletri was approved by the FDA under a unique NDA. Veletri has the same non-proprietary name as other epoprostenol products. However; Veletri is not therapeutically equivalent to these products. The primary speaker stated that Veletri, a new formulation, was updated in June 2012. The new formulation has greater stability than other epoprostenol-based products and once reconstituted can be stored for up to 8 days.

Final Decision:

The CMS HCPCS Workgroup reconvened to reconsider this application together with all input provided. CMS upheld its decision not to establish a new code. 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.

HPCPS 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, intravenous, 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 isavuconazonium sulfate (equivalent to 200 mg isavuconazole). Capsules contain 186 mg isavuconazonium sulfate (equivalent to 100 mg isavuconazole). 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

Summary of Primary Speaker Comments at the Public Meeting:

There was no primary speaker for this item.

Final Decision:

CMS upheld its decision. We are pleased to inform you that the following modification has been made to the HCPCS Level II standard, national code set:

Establish J1833 Injection, Isavuconazonium, 1mg

HPCPS 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

Summary of Primary Speaker Comments at the Public Meeting:

The primary speaker provided at CMS' HCPCS Public Meeting in agreement with our preliminary decision.

Final Decision:

Establish code J0714: Injection, Ceftazidime and Avibactam, 0.5g/0.125g

PAYMENT FOR PART B DRUGS, BIOLOGICALS, BIOSIMILARS, AND RADIOPHARMACEUTICALS

Background

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

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

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

Drugs Paid on a Cost or Prospective Payment Basis

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

Part B Drug Payment Methodology

Historical Payment Methodology

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

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

Current Methodology

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

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

In accordance with Section 1847A of the Social Security Act, as established in the MMA, CMS has been reviewing its coding and pricing determinations to ensure that separate and appropriate payment is made for single source drugs and biologics as required by this section of the Act. In order to facilitate separate and appropriate payment, it may be necessary to create unique HCPCS level II codes for certain products. CMS has continued to review how we operationalize the terms ‘single source drug,’ ‘multiple source drug,’ and ‘biological product’ in the context of payment under section 1847A to identify the potential need to make any changes to our assignment of National Drug Codes (NDCs) to billing codes for payment purposes. Also, in accordance with revisions to section 1847A of the Social Security Act made by the Affordable Care Act, CMS will incorporate biosimilars that are approved under the abbreviated biological approval pathway into the ASP payment methodology, and will issue additional guidance as necessary.

So that we can implement coding and pricing changes swiftly, CMS has used and will continue to use its internal process, when appropriate, for modifying

the code set. Please be aware that internally generated code requests are not part of the HCPCs public meeting process.

Exceptions to ASP pricing methodology

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

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

Payment for Radiopharmaceuticals

The payment methodology for radiopharmaceuticals did not change under the MMA. Specifically, Section 303(h) states that “[n]othing in the amendments . . . shall be construed as changing the payment methodology . . . for radiopharmaceuticals . . .” Payment for radiopharmaceuticals administered in the physician’s office is determined by Medicare administrative contractors (MACs).

Part B versus Part D

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

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