Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Public Meeting Summary Report
Drugs, Biologicals, and Radiopharmaceuticals Radiologic Imaging Agents
Wednesday, May 18, 2016

Introduction and Overview

Approximately 55 people attended. The agenda included 11 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.

Felicia Eggleston, from the Division of CMM's Hospital and Ambulatory Policy Group provided an overview of Medicare's Part B Drugs payment (DAS), provided an overview of the Medicare payment methodology for Part B drugs, biologicals, and radiopharmaceuticals. A copy of the overview was provided in a written document and is attached to this summary.

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

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

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

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

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

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

HCPCS Public Meeting Agenda Item # 1

May 18, 2016

Application# 16.028

TOPIC

Request to establish new Level II HCPCS code to identify a Lysosomal Acid Lipase (LAL) enzyme replacement (sebelipase alfa), Trade Name: KANUMA.

Applicant's suggested language: JXXXX: "Injection sebalipase alfa, 1 mg".

BACKGROUND

Alexion Pharmaceuticals, Inc. submitted a request to establish a new Level II HCPCS code to identify KANUMA (sebelipase alfa). According to the applicant, KANUMA is a recombinant human lysosomal acid lipase (rhLAL) enzyme replacement therapy for the treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency. KANUMA binds to cell surface receptors via glycans expressed on the protein and is subsequently internalized into lysosomes. Sebalipase alfa catalyzes the lysosomal hydrolysis of cholesteryl esters and triglycerides to free cholesterol, glycerol, and free fatty acids.

KANUMA is administered via intravenous infusion. The recommended dosage is 1mg/kg administered once every other week. For patients with rapidly progressive LAL deficiency presenting within the first 6 months of life, the recommended dosage is 1 mg/kg administered once weekly as an initial dose.

KANUMA is supplied in single-use vials containing 10.5 mL solution and a total extractable volume of 10mL at 2mg/mL.

The applicant comments a new code is warranted because no existing code adequately describes KANUMA.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX "Injection, sebelipase alfa, 1 mg".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS' HCPCS workgroup for granting (KAMULA) a unique J code and agreed with our preliminary decision.

HCPCS Public Meeting Agenda Item # 2

May 18, 2016

Application# 16.030

TOPIC

Request to discontinue existing code J8565 “Gefitinib, oral, 250mg”.

BACKGROUND

AstraZeneca Pharmaceuticals LP submitted a request to discontinue existing code J8565 “Gefitinib, oral, 250mg”. This code describes IRESSA. According to the applicant, IRESSA is a tyrosine kinase inhibitor indicated as monotherapy for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) after failure of both platinum-based and docetaxel chemotherapies.

The recommended dose is 250 mg orally, once daily with or without food. IRESSA was among the drugs chosen for the Medicare Replacement Drug program in which frequently-used physician administered therapies were replaced by oral or self-administered alternatives in an effort to evaluate patient access to care and the impact on Medicare spending.

The applicant comments that code J8565 should be discontinued for the following reasons: the FDA requested that AstraZeneca voluntarily withdraw IRESSA from the market in August 2010, because the post-marketing studies failed to verify and confirm a clinical benefit; as IRESSA is an oral anti-cancer drug with no IV equivalent, a J code for IRESSA is unnecessary; and “IRESSA is not eligible for reimbursement”. Therefore, the existence of the code is confusing and creates an administrative burden.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to discontinue existing code J8565 "Gefitinib, oral, 250 mg" has not been approved. The drug is still available in the marketplace.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision and reiterated the original request to discontinue existing code J8565 "Gefitinib, oral 250 mg". The speaker commented that code J8565 should be discontinued for the following reasons: (1) IRESSA has no IV equivalent and as such code J8565 inappropriately differentiates IRESSA from other oral cancer drugs, and is obsolete; (2) IRESSA is not covered under Medicare Part B; and (3) maintaining code J8565 requires ongoing review and confirmation as such, and creates an unnecessary administrative burden for CMS.

HCPCS Public Meeting Agenda Item # 3

May 18, 2016

Application# 16.031

TOPIC

Request to establish a Level II HCPCS code to identify a recombinant hemophilic factor, Trade Name: NUWIQ.

Applicant's suggested language: "JXXXX - Injection, factor viii (antihemophilic factor, recombinant), (NUWIQ), per I.U.".

BACKGROUND

Octapharma USA Inc. submitted a request to establish a new Level II HCPCS code to identify NUWIQ. According to the applicant, NUWIQ is a recombinant B-domain deleted Coagulation Factor VIII product derived from Human Embryonic Kidney (HEK) cells. NUWIQ behaves in the same way as endogenous human factor VIII in native human plasma. Thus, administration of NUWIQ temporarily allows correction of the hemostatic abnormalities in Hemophilia A patients.

NUWIQ is indicated in adults and children with Hemophilia A in the following cases. First, as an on-demand treatment and control of bleeding episodes. Second, as perioperative management of bleeding. Third, as routine prophylaxis to reduce the frequency of bleeding episodes.

NUWIQ is delivered via an intravenous infusion, with the dose for adults and adolescents determined according to the following formula: Required IU = body weight (kg) x desired Factor VIII rise (%) (IU/dL) x 0.5 (IU/kg per IU/dL). Dosing for routine prophylaxis for adolescents 12-17 years of age is 30-40 IU/kg every other day; and for children 12 years of age is 30-50 IU/kg every other day or three times per week. NUWIQ is supplied in a single-use vials containing nominal Factor VIII potencies of 250, 500, 1000 or 2000 IU.

The applicant comments that the request for a temporary code is warranted in order to uniquely identify NUWIQ.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX "Injection, factor viii (antihemophilic factor, recombinant), (NUWIQ), 1 i.u.".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. The applicant submitted written comments in agreement with the CMS' HCPCS preliminary coding decision.

HCPCS Public Meeting Agenda Item # 4

May 18, 2016

Application# 16.047

TOPIC

Request to establish a new Level II HCPCS code to identify a plasma-derived human blood coagulation Factor X, Trade Name: COAGADEX.

Applicant's suggested language: "JXXXX, Injection, Coagulation Factor X (Human) [COAGADEX], per unit".

BACKGROUND

Bio Products Laboratory, Inc. submitted a request to establish a new Level II HCPCS code to identify COAGADEX. According to the applicant, COAGADEX is a plasma-derived coagulation Factor X that temporarily replaces the missing Factor X needed for effective hemostasis. COAGADEX is indicated in adults and children (aged 12 and up) with hereditary Factor X deficiency for on-demand treatment and control of bleeding episodes. It is also indicated for the perioperative management of bleeding in patients with mild hereditary Factor X deficiency. However, there is a limitation of use since the perioperative management of bleeding in major surgery has not been studied in patients with moderate and severe hereditary Factor X deficiency.

For on-demand treatment and control of bleeding episodes, 25 IU/kg of COAGADEX should be infused when the first sign of bleeding occurs. The dose may be repeated at intervals of 24 hours until the bleeding stops. For the perioperative management of bleeding, the pre-surgery dose of COAGADEX is calculated to raise plasma Factor X Levels to 70-90 IU/dL. Post-surgery, repeat doses should be administered as necessary to maintain plasma Factor X Levels at a minimum of 50 IU/dL until the patient is no longer at risk of bleeding due to surgery.

COAGADEX is supplied in single-use vials containing a nominal (approximate) 250 IU or 500 IU (approximately 100 IU/mL after reconstitution) of Factor X activity, packaged with 2.5 mL of 5 mL of Sterile Water for Injection, respectively, and a Mix2Vial transfer device.

The applicant comments that a new code is warranted because there is no existing Level II HCPCS code that describes COAGADEX. Currently, there are no other drug/biologic products for Factor X.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX "Injection, Factor X (Human), 1 i.u.".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item # 5

May 18, 2016

Application# 16.036

TOPIC

Repeat request to establish a new Level II HCPCS code to identify phenylephine and ketorolac injection used during cataract surgery and IOL replacement procedures, Trade Name: Omidria.

Applicant's suggested language: "JXXXX, Injection, phenylephrine and ketorolac 1%/0.3%, 4-mL vial".

BACKGROUND

Omeros Corporation submitted a request to establish a new Level II HCPCS code to identify Omidria. According to the applicant, Omidria is a drug used during cataract surgery. It is solution containing 12.4 mg/mL of phenylephrine hydrocholoride and 4.24 mg/mL ketorolac tromethamine in a single-patient use vial. It is to be diluted in 500 mL of ophthalmic irrigating solution and used as needed during cataract surgery and intraocular lens (IOL) replacement procedures to maintain pupil size by preventing intraoperative miosis to reduce postoperative ocular pain.

The applicant comments that a permanent J code for Omidria would enable providers to appropriately report use and establish payment. Currently, other J codes exist for the active ingredients in Omidria, which causes confusion and improper use of billing codes. In addition, the current C code assigned to Omidria, C9447, cannot be reported when Omidria is used in a physician’s office. Hence, a separate J code is required for an injectable drug used in a physician’s office setting.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify Omidria has not been approved, because this product is an integral part of a procedure and payments for that service includes payment for Omidria if it is used. Existing code C9447 "Injection, Phenylephrine and ketorolac, 4 mL vial" is available for assignment by insurers if they deem appropriate, to report use of Omidria in a hospital outpatient setting.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision. The speaker commented that a unique J code is needed to ensure patient access to Omidria, and to avoid confusion with existing codes J1885 and J2730 which identify the active ingredients in Omidria. The speaker also commented that non-Medicare insurers "do not recognize" C codes; and C codes "will not be recognized" for cataract surgery performed in a physician office.

HCPCS Public Meeting Agenda Item # 6

May 18, 2016

Application# 16.043

TOPIC

Request to establish a new Level II HCPCS code to identify an epidermal growth factor receptor (EGFR) antagonist, (necitumumab), Trade Name: PORTRAZZA.

Applicant's suggested language: "J9XXX – injection, necitumumab, 100mg".

BACKGROUND

Eli Lilly and Company submitted a request to establish a new Level II HCPCS code to identify PORTRAZZA (necitumumab). According to the applicant, PORTRAZZA is a physician-administered anti-cancer agent. PORTRAZZA is indicated, when used in combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer. PORTRAZZA is a recombinant human IgG1 monoclonal antibody that binds to human epidermal growth factor (EGFR) and blocks the binding of EGFR to its ligands.

PORTRAZZA is administered on days 1 and 8 of each 3-week cycle, with treatment continuing until progression or unacceptable toxicity. The recommended dose is 800mg (absolute dose), which is delivered via a 60-minute intravenous infusion. PORTRAZZA is supplied as a single dose vial containing 800mg/50mL.

The applicant comments that a new code is warranted because, without a drug-specific code, the product will be billed under miscellaneous HCPCS codes, which require additional provider documentation for submission and review.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish J9XXX "injection, necitumumab, 1 mg".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item # 7

May 18, 2016

Application# 16.056

TOPIC

Request to revise the descriptor of existing code J7297. Currently, the code reads, “Levonorgestrel-releasing intrauterine contraceptive system, 52mg, 3 year duration”.

Applicant’s suggested revised language for J7297: “levonorgestrel-releasing intrauterine contraceptive system, 52 mg, indicated for both nulliparous and parous women".

BACKGROUND

Actavis, Inc., an Allergan company, submitted a request to revise existing code J7297, so as to remove the phrase “3 year duration” from the code, and to replace it with “indicated for both nulliparous and parous women". According to the applicant, Liletta is an effective form of long-acting reversible contraception. It is inserted in the intrauterine cavity by a healthcare provider using the included inserter. It can be removed at any time but must be removed by the end of the third year. It can be replaced at the time of removal with a new Liletta if continued contraceptive protection is desired.

Liletta contains 52 mg Levonorgestrel and is packaged with an inserter in one sterile unit.

The applicant comments that a revision to the code text is needed because, although Liletta is currently indicated for the prevention of pregnancy for up to 3 years, there is an ongoing clinical trial for a longer duration of use, for up to 7 years. If the FDA approves a longer duration of use for Liletta, the current code descriptor for J7297 will no longer be accurate, and there would be no other existing code that would accurately describe Liletta. The recommended revision would provide a better description of Liletta, regardless of FDA-approved duration of use, and would maintain coding stability and predictability for providers and payers.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to revise the descriptor to an existing Level II HCPCS code has not been approved, because the proposed revision does not improve the code. The existing code J7297 "Levonorgestrel-releasing intrauterine contraceptive system, 52mg, 3 year duration" adequately describes the product that is the subject of this application.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision, stating that a code specifying duration of use will become obsolete each time the FDA clears a longer duration of use. And, since CMS' HCPCS coding cycle is asynchronous with FDA label changes, the most robust code would not describe duration of use. The speaker reiterated the original request to identify LILETTA based on milligram strength and approved indications of use.

HCPCS Public Meeting Agenda Item # 8

May 18, 2016

Application# 16.057

TOPIC

Request to establish a new Level II HCPCS code to identify a radioactive diagnostic agent, Trade Name: Choline C11 Injection.

Applicant's suggested language: "AXXXX: Choline C-11 injection, diagnostic, per study dose, up to 20 mCi".

BACKGROUND

Zevacor Molecular submitted a request to establish a new Level II HCPCS code to identify Choline C11 Injection. According to the applicant, Choline C11 Injection is a radioactive diagnostic drug indicated for use during PET imaging of patients with biochemical (Elevated/Rising PSA) prostate cancer recurrence and non-informative bone scintigraphy, CT or MRI. ^{11}C-Choline PET imaging may help identify potential sites of prostate cancer recurrence for subsequent histologic confirmation. Suspected prostate recurrence is based upon elevated blood prostate specific antigen (PSA) Levels following initial therapy. ^{11}C-choline PET imaging is not a replacement for histologic verification of recurrent prostate cancer.

Choline C11 Injection is a radiolabeled analog of choline, a precursor molecule essential for the biosynthesis of cell membrane phospholipids. Choline is involved in synthesis of the structural components of cell membranes, as well as modulation of trans-membrane signaling. Increased phospholipid synthesis (i.e., increased uptake of choline) has been associated with cell proliferation and the transformation process that occurs in tumor cells.

Choline C11 Injection is supplied as a single patient dose syringe, containing 148 MBq to 1225 MBq (4 mCi to 33.1 mCi) per mL of ^{11}C-choline at end of synthesis calibration time in 0.9% aqueous NaCl solution (approximately 10 mL volume). The recommended dose is 370 to 740 MBq (10 to 20 mCi), administered as a bolus intravenous injection.

The applicant comments that a new code is warranted because no existing Level II HCPCS code identifies the product, nor is there an appropriate unlisted code. Further, current CMS policy precludes billing for PET scans in conjunction with HCPCS code A4641 (Radiopharmaceutical, diagnostic, not otherwise classified), effective 2008.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish "AXXXX, Choline C-11, diagnostic, 1 millicurie".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with the CMS' preliminary decision to establish a new code, but disagreed with CMS' proposed dose descriptor. The speaker reiterated the original request for a code with a "per study dose" descriptor, based on existing precedent with other radiopharmaceutical HCPCS codes; inconsistency with the current pass-through code descriptor; and the challenges with billing due to the short shelf life of this product.

HCPCS Public Meeting Agenda Item # 9

May 18, 2016

Application# 16.058

TOPIC

Request to establish a new Level II HCPCS code to identify a diagnostic radiopharmaceutical, (Florbetaben [F 18 Injection]), Trade Name: Neuraceq.

Applicant's suggested language: "AXXXX: Neuraceq (Florbetaben (F 18 Injection, diagnostic, per study dose, up to 8.1 millicures))."

BACKGROUND

Piramal Imaging, Inc. submitted a repeat request to establish a new Level II HCPCS code to identify Neuraceq (florbetaben F 18). According to the applicant, Neuraceq is a diagnostic radiopharmaceutical used with Positron Emission Tomography (PET) imaging of the brain to estimate B-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline. Neuraceq has a physical half-life of 110 minutes and a shelf-life of 10 hours.

Neuraceq is supplied to an imaging center in a single patient-unit dose. Patients receive a slow, single IV bolus of 300MBq (8.1 mCi) (6 sec/mL) of Neuraceq in a total volume of up to 10 mL, followed 45-130 minutes afterwards by a brain PET imaging for 15-20 minutes in duration.

The applicant comments that a new code is warranted because no existing code adequately describes Neuraceq. Existing code descriptors are not specific to Neuraceq's active ingredient, florbetaben F-18.

PRELIMINARY HCPCS CODING RECOMMENDATION

Newly established code Q9983 QXXXX "Florbetaben f18, diagnostic, per study dose, up to 8.1 millicuries", effective 7/1/16, adequately describes the product that is the subject of this request.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary decision, to add a code effective 7/1/16 but asked that the new code be "a permanent A code", rather than a Q code.

HCPCS Public Meeting Agenda Item # 10

May 18, 2016

Application# 16.066

TOPIC

Repeat request to establish a new Level II code to identify a diagnostic radiopharmaceutical Flutemetamol F18, Trade Name: Vizamyl.

Applicant's suggested language: "AXXXX, Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries".

BACKGROUND

GE Healthcare submitted a request to establish a new Level II HCPCS code to identify Vizamyl (Flutemetamol F18 Injection). According to the applicant, Vizamyl is a diagnostic radiopharmaceutical indicated for use with PET imaging of the brain to estimate B-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) or other causes of cognitive decline.

The recommended dose of Vizamyl is 185 megabecquerels (MBq) (5 milliCuries (mCi); maximum mass dose 20 micrograms) in a maximum dose volume of 10 mL. It administered as a single intravenous bolus within 40 seconds, followed by an intravenous flush of 5-15 mL, of 0.9 sterile sodium chloride injection.

The applicant suggested that the requested new code replace existing code C9459 "Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries" and A9599 "Radiopharmaceutical, diagnostic, for beta-amyloid positron emission tomography (pet) imaging, per study dose".

PRELIMINARY HCPCS CODING RECOMMENDATION

Newly established code Q9982 "Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries", effective 7/1/16, adequately describes the product that is the subject of this application.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with the CMS preliminary decision to establish a new code effective 7/1/16, but asked that the code be a permanent A code instead of the temporary Q code. The speaker stated that assignment of a Q code puts the manufacturer of this product at a competitive disadvantage to another radiopharmaceutical company. The speaker indicated that all beta amyloid agents should have parallel coding assignments to ensure equal treatment with respect to coverage and reimbursement

HCPCS Public Meeting Agenda Item # 11

May 18, 2016

Application# 16.062

TOPIC

Request to establish new Level II HCPCS code to identify a monoclonal antibody (daratumumab), Trade Name: DARZALEX.

Applicant's suggested language: "JXXXX, IV infusion, daratumumab, per 1mg".

BACKGROUND

Janssen Biotech, Inc. is requesting a new HCPCS code for DARZALEX (daratumumab). According to the applicant, daratumumab is a human CD38-directed monoclonal antibody indicated for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double-refractory to a PI and an immunomodulatory agent.

Daratumumab binds to CD38 and inhibits the growth of CD-38-expressing tumor cells by inducing apoptosis directly through Fc mediated cross linking, as well as by immune-mediated tumor cell lysis through complement dependent cytotoxity (CDC), antibody-dependent cell-mediated cytotoxity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).

Daratumumab is to be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage infusion reactions if they should occur. Pre-infusion and post-infusion medications are required.

Daratumumab is supplied as a solution for intravenous infusion in single dose vials. NDC 57894-502-05 contains one 100mg/5mL (20mg/mL) in a single dose vial. NDC 57894-502-20 contains one 400 mg/20mL (20mg/mL) in a single dose vial. The recommended dose of Daratumumab is 16 mg/kg body weight for the following timeframes: weekly, for weeks 1-8; every two weeks, for weeks 9-24; and every four weeks, for weeks 25 onwards until disease progression.

The applicant comments that there are no existing codes or similar products on the market, and a new code will describe DARZALEX and allow physicians to accurately report and payers to capture important product-specific information.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish J9XXX "Injection, daratumumab, 10 mg".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. The applicant submitted written comments to the CMS HCPCS workgroup in agreement with our preliminary decision.

HCPCS Public Meeting Agenda Item # 12

May 18, 2016

Application# 16.065

TOPIC

Request to establish a new Level II HCPCS code to identify an oil-based radiopaque contrast agent (Ethiodized Oil), Trade Name: Lipiodol.

Applicant's suggested language: "A95XX (ethiodized oil, per 2 mL)".

BACKGROUND

Guerbet, LLC submitted a request to establish a new Level II HCPCS code to identify Lipiodol (Ethiodized Oil). According to the applicant, Lipiodol is an oil-based radiopaque contrast agent indicated for: hysterosalpingography in adults; lymphography in adult and pediatric patients; and selective hepatic intra-arterial use for imaging tumors in adults with known hepatocellular carcinoma (HCC). Selective tumor uptake of Lipiodol after injection into the hepatic artery provides image guidance and visualization in adults with known HCC tumors.

For hysterosalpingography, inject Lipiodol into the endometrial cavity with fluoroscopic control. For lymphography, inject Lipiodol into a lymphatic vessel under radiologic guidance to prevent inadvertent venous administration or intravasation. Lipiodol Ethiodized Oil is a sterile injectable radio-opaque diagnostic agent. It is supplied within a 10 mL ampoule. Each mL of Lipiodol contains 480 mg/mL of Iodine organically combined with ethyl esters of fatty acids of poppy seed oil.

The applicant comments that a new code is warranted because no existing HCPCS code adequately describes Lipiodol.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify Lipiodol has not been approved, because this product is an integral part of a procedure, and payment for that service includes payment for Lipiodol if it is used.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item # 13

May 18, 2016

Application# 16.059

TOPIC

Request to establish new Level II HCPCS code to identify a fluoroquinolone antibacterial (ciprofloxacin otic suspension), Trade Name: OTIPRIO.

Applicant's suggested language: either "JXXXX, ciprofloxacin thermosensitive otic suspension, per single-patient use vial" or "JXXXX, ciprofloxacin thermosensitive otic suspension, up to 0.2 mL per single-patient use vial".

BACKGROUND

Otonomy, Inc. submitted a request to establish a new Level II HCPCS code to identify OTIPRIO (ciprofloxacin otic suspension). According to the applicant, OTIPRIO is the only product approved by the FDA for the treatment of pediatric patients with bilateral otitis media with effusion undergoing tympanostomy tube placement. OTIPRIO has thermosensitive properties, such that, at room temperature or below, it exists as a liquid and transitions to a gel after exposure to body temperature in the middle ear.

OTIPRIO is supplied as an otic suspension of 6% (60 mg/mL, w/v) ciprofloxacin in neutral pH buffered, isotonic solution containing poloxamer 407, a glycol polymer. Each single-patient use vial contains 1 mL, but because of the poloxamer and thermosensitive properties of OTIPRIO, only two 0.1 mL doses (one per ear) can be withdrawn from a single-patient use vial. OTIPRIO is administered by an intratympanic injection of 0.1 mL into each ear by the physician during tympanostomy tube placement. The dose administered for a single patient is 0.2 mL total.

The applicant comments that a new code is warranted because there are no existing Level II HCPCS codes that describe ciprofloxacin thermosensitive otic suspension.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify OTIPRIO has not been approved, because this product is an integral part of a procedure, and payment for that service includes payment for OTIPRIO when it is used.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with the CMS' preliminary decision, stating that a permanent J code is needed to report the use of OTIPRIO when the procedure is performed in a physician's office and other settings.

HCPCS Public Meeting Agenda Item # 14

May 18, 2016

Application# 16.068

TOPIC

Request to establish a new Level II HCPCS code to identify a topoisomerase inhibitor (irinotecan liposome injection), Trade Name: ONIVYDE.

Applicant's suggested language: "J9XXX - Injection, irinotecan liposome, 1 mg".

BACKGROUND

On behalf of Merrimack Pharmaceuticals, a request was submitted to establish a new Level II HCPCS code to identify ONIVYDE (irinotecan liposome injection). According to the applicant, ONIVYDE is a novel encapsulation of irinotecan in liposomal formulation. It is indicated in combination with fluorouracil and leucovorin, for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.

ONIVYDE is administered via IV infusion. The recommended dose is 70mg/mx2, administered by IV infusion over 90 minutes every 2 weeks. ONIVYDE is supplied as a single-dose vial, containing 43mg/10mL irinotecan free base (NDC 69171-0398-01).

The applicant comments that a new code is warranted because no existing code describes ONIVYDE, and a new code will ensure appropriate ASP-based payment under section 1847A of the Social Security Act.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish J9XXX "Injection, irinotecan liposome, 1 mg".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

HCPCS Public Meeting Agenda Item # 15

May 18, 2016

Application# 16.029

TOPIC

Request to establish a new Level II HCPCS code to identify a biosimilar tumor necrosis factor alpha blocker (infliximab), Trade Name: Inflectra.

Applicant's suggested language: "JXXXX (Injection, infliximab biosimilar, 10 mg)".

BACKGROUND

Hospira, a Pfizer company, submitted a request to establish a new level II HCPCS code to identify Inflectra. According to the applicant, Inflectra is a tumor necrosis factor alpha (TNFα) blocker. Infliximab neutralizes the biological activity of TNFα by binding with high affinity to the soluble and transmembrane forms of TNFα and inhibits binding of TNFα with its receptors. Infliximab does not neutralize TNFβ (lymphotoxin-α), a related cytokine that utilizes the same receptors as TNFα. Inflectra has the same indications as Remicade: Crohn's disease, pediatric Crohn's disease, ulcerative colitis, pediatric ulcerative colitis, rheumatoid arthritis in combination with methotrexate, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.

Inflectra is administered by intravenous infusion over a period of not less than 2 hours. The recommended dose varies according to which of the above-mentioned diseases is being treated. Each Inflectra 20 mL vial contains 100 mg of infliximab for final reconstitution volume of 10 mL.

The applicant comments that existing code J1745 "Injection infliximab, 10 mg" is insufficient to report Inflectra, because, in order to apply the specified payment amount for a biosimilar product as required by the Affordable Care Act, a new HCPCS code will be required for the biosimilar. For this reason, the applicant requests the addition of a new code for Inflectra.

PRELIMINARY HCPCS CODING RECOMMENDATION

1) Establish modifier ZB Pfizer/Hospira. Effective 7/1/16.

2) Establish Q5102 "Injection, infliximab biosimilar, 10 mg". Effective 7/1/16.

3) Revise existing code J1745, which currently reads "Injection infliximab, 10mg", to instead read, "Injection, infliximab, excludes biosimilar, 10mg". Effective 1/1/17.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker offered comments at the CMS HCPCS Public Meeting thanking CMS and expressing agreement with the workgroup's preliminary decision.