Centers for Medicare & Medicaid Services (CMS)
Healthcare Common Procedure Coding System (HCPCS)
Application Summaries for Drugs, Biologicals and Radiopharmaceuticals

Tuesday, May 16, 2017

This HCPCS Code Application Summary document includes a summary of each HCPCS code application discussed at the May 16, 2017 HCPCS Public Meeting for Drugs, Drugs, Biologicals and Radiopharmaceuticals and Radiologic Imaging Agents. HCPCS code applications are presented within the summary document in the same sequence as the Agenda for this Public Meeting. Each individual summary includes: the application number, topic; background/discussion of the applicant's request; CMS' published preliminary HCPCS coding recommendation; CMS' published preliminary Medicare payment recommendation; a summary of comments offered on behalf of each applicant at CMS' HCPCS public meeting in response to our preliminary recommendations; and CMS' final HCPCS coding decision. We publish a separate HCPCS Code Application Summary document for each HCPCS Public Meeting held. This is one of a series of five HCPCS Code Application Summaries for CMS' 2017-2018 HCPCS coding cycle.

Introduction and Overview

Approximately 75 people attended. The agenda included 15 items.

Cindy Hake, Director, CMS National Level II HCPCS Coding Program and Deputy Director, Division of DMEPOS Policy, provided an overview of the HCPCS public meeting procedures as it relates to the overall HCPCS coding process.

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

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

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

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

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: www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.html.

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: HCPCS Decision Tree - cms.gov.

Tuesday, May 16, 2017

Agenda Item # 1

Application# 17.012

TOPIC

Request to establish a new Level II HCPCS code to identify ocrelizumab; Trade name: OCREVUS.

Applicant's suggested language is: "JXXXX - Injection, ocrelizumab, 1 mg".

BACKGROUND

Genetech has requested a new Level II HCPCS code to identify ocrelizumab; Trade name OCREVUS. According to the applicant, OCREVUS is a recombinant humanized monoclonal antibody indicated for the treatment of patients with relapsing or primary progressive forms of multiple sclerosis.

OCREVUS selectively targets CD20-expressing B-cells. The precise mechanism through which OCREVUS exerts its clinical effects in MS is not fully elucidated but presumed to involve immunomodulation through the reduction in the number and function of CD20-expressing B-cells. Following surface binding, OCREVUS selectively depletes CD20-expressing B-cells through antibody-dependent cellular phagocytosis, antibody-dependent cellular cytoxiticy, complement-dependent cytotoxity, and apoptosis. The capacity of B-cell reconstitution and preexisting humoral immunity are preserved. In addition, innate immunity and total T-cell numbers are not affected. The recommended dose of OCREVUS is 600 mg administered as an intravenous infusion every 6 months. The initial 600mg dose is split into two separate 300mg IV infusions to be administered two weeks apart.

OCREVUS injection for intravenous infusion is supplied as 30 mg/mL ocrelizumab in 20 mM sodium acetate, 106 mM trehalose dihydrate and 0.02% (w/v) polysorbate 20 at pH 5.3. The drug product is supplied at a volume of 10 mL in a 15 mL glass vial. Each carton contains one 300 mg/10 mL single-use vial.

The applicant comments that a new code is needed because OCREVUS is a new, unique biological compound not identified by existing codes.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, ocrelizumab, 1 mg". Effective 1/1/18.

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Agenda Item # 1 (continued)

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION:

Establish J2350, "Injection, ocrelizumab, 1 mg".

Tuesday, May 16, 2017

Agenda Item # 2

Application# 17.002

TOPIC

1. Request to establish a new Level II HCPCS code to identify STELARA® (ustekinumab) for intravenous infusion.

Applicant's suggested language: JXXXX: Injection, ustekinumab, 130 mg (one vial), for intravenous infusion.

2. Request to revise existing HCPCS code J3357 which currently reads:" Injection, ustekinumab, 1 mg" to instead read:" Injection,ustekinumab, 1 mg , for subcutaneous injection", to clearly distinguish its use from the code for the IV formulation.

Applicant's suggested language: J3357 "Injection, ustekinumab, 1mg, for subcutaneous injection" to replace the prior description, "Injection, ustekinumab, 1mg."

BACKGROUND

Janseen Biotech, Inc., submitted a request to establish a new Level II HCPCS code to identify STELARA® (ustekinumab), for intravenous infusion, and to revise existing code J3357 to distinguish it from the IV formulation. According to the applicant, STELARA is a human interleukin-12 and -23 antagonist indicated as an induction dose for treatment of patients with severe active Crohn's disease (CD) who have failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or failed or were intolerant to treatment with one or more TNF blockers. STELARA® (ustekinumab) is a biological for intravenous infusion and has no other useful purpose in the absence of illness. Patients are treated by subcutaneous injections. These induction doses must be administered as one-hour intravenous doses.

STELARA® is for use as an intravenous infusion and is available as 130 mg of usetekinumab in 26mL, supplied as a single use 30mL vial.

The applicant comments that a new code to identify the IV formulation is warranted, due to the IV's product's larger loading dose, its lower cost, and its single FDA approved use for induction therapy. The first key clinical distinction is that STELARA® IV has one clinical purpose, induction therapy for treatment of patients with Crohn's disease. The induction therapy quickly raises the initial blood levels so that the IL-17 and IL-13 blockade is most effective. The initial blockade is not obtained with subcutaneous administration.

PRELIMINARY HCPCS CODING RECOMMENDATION

1) Established Q9989, "Ustekinumab, For Intravenous Injection, 1mg." Effective 7/1/17.

2) Discontinue Q9989. Effective 12/31/17.

3) Establish new code JXXXX with same language as Q9989, "Ustekinumab, For Intravenous Injection, 1mg." Effective 1/1/18.

New code Q9989 adequately describes STELARA.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked the HCPCS Work Group and indicated agreement with the preliminary recommendation. The primary speaker also complimented the HCPS team for its support and high level of responsiveness during the application process.

FINAL DECISION:

1) Establish Q9989, "Ustekinumab, For Intravenous Injection, 1mg." Effective 7/1/17.

2) Discontinue Q9989. Effective 12/31/17.

3) Establish new code J3358 with same language as Q9989, "Ustekinumab, For Intravenous Injection, 1mg." Effective 1/1/18.

New code Q9989 adequately describes STELARA.

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Agenda Item # 3

Application# 17.025

TOPIC

Request to revise the dose descriptor of existing HCPCS code A9587 which currently reads: "Gallium Ga-68, dotatate, diagnostic, 0.1 mCi"; to instead read: "A9587, Gallium Ga-68, dotatate, diagnostic, to per study dose, up to 5.4 mCi".

BACKGROUND

Advanced Accelerator Applications, USA, Inc., submitted a request to identify a kit for preparation of Gallium-68 dotatate injection, Trade Name: NETSPOT. According to the applicant, NETSPOT is an agent for positron emission tomography imaging for localization of neuroendocrine tumors. Ga 68 dotate has a high affinity for somatostatin subtype 2 receptors. Galllium-68 is a B+ emitting radionuclide with a 68-minute half-life, and a high emission yield, properties favorable to PET imaging.

The recommended dose is 2 MBq/kg body weight (0.054 mCi/kg) up to 200 MBq (5.4 mCi). Although doses smaller than 5.4 mCi may be ordered, the price is the same per unit dose because one kit must be used per dose. NETSPOT is supplied as a single-dose kit for direct preparation of Gallium-Ga-68, dotate, injection with dotatate and Gallium-68 chloride solution eluted from a Germanim-68/Gallium-68 generator (supplied separately) and with a reaction buffer.

The applicant comments that the current descriptor (0.1 mCi) requires providers to submit claims with up to 54 units while the product is purchased as a single unit regardless of the radioactivity. Additionally, the delivered dose can be +/- 10% of the prescribed dose, which could lead to errors on claims and unnecessary administrative burden.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to revise the descriptor of existing code A9587 has not been approved. The requested change does not improve the code. The existing descriptor of A9587, which reads, "Gallium ga-68, dotatate, diagnostic, 0.1 millicurie", adequately describes the product that is the subject of this request and is available for assignment by insurers if they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision, urging CMS to reconsider its decision and revise existing HCPCS code A9587 for the following reasons. "The FDA approved NETSPOT® as a single dose kit where only one unit dose is derived from each kit. After radiolabeling with Gallium-68, NETSPOT® is a radioactive diagnostic agent indicated for use with positron emission tomography (PET) imaging for localization of neuroendocrine tumors

(NETs). The cost of product is the same for each dose regardless of the radioactivity and the Redbook® listing is based on a unit dose. 98% of prescribed doses are at or greater than 4.8 mCi (within 10% max dose). The current descriptor (0.1mCi) would require the providers to submit claims with units of 54 units while the product is purchased as a single unit dose regardless of the amount of the radiolabel. Additionally, per the FDA label, the delivered dose can be +/- 10% of prescribed dose, which could lead to errors on the claims and unnecessary administrative burden. Finally, diagnostic PET radiopharmaceuticals are typically described as 'per study dose' and the code descriptor for NETSPOT® would be inconsistent with the other descriptors."

FINAL DECISION:

This request to revise the descriptor of existing code A9587 has not been approved. The requested change does not improve the code. The existing descriptor of A9587, which reads, "Gallium ga-68, dotatate, diagnostic, 0.1 millicurie", adequately describes the product that is the subject of this request and is available for assignment by insurers if they deem appropriate.

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Agenda Item # 4

Application# 17.061

TOPIC

Request to revise existing HCPCS code A9588 which currently reads: "fluciclovine 18F, diagnostic 1 mCi," to instead read: "Fluciclovine F-18, diagnostic, per study dose". Trade Name: Axumin.

BACKGROUND

Blue Earth Diagnostics submitted a request to revise the dose descriptor of existing code A958 for fluciclovine, Trade Name: Axumin.

According to the applicant, Axumin is a radioactive diagnostic agent for PET imaging for men with suspected prostate cancer reoccurrence. It is an amino acid transporter across mammalian cell membranes by amino acid transporters for imaging patients with a biochemical reoccurrence of prostate cancer. Axumin PET imagining of men with reoccurrence may identify sites of reoccurrence based upon elevated blood levels of PSA following initial therapy.

Axumin has a physical half-life of 109.7 minutes. It is supplied as a 10mCi patient-ready dose at the time of calibration. The recommended dose is 370MBq (10mCi) administered as an IV bolus injection.

The applicant comments that the current code descriptor does not adequately describe the product because Axumin is never prescribed in 1mCi increments. A "per study dose" would reduce confusion surrounding billing of activity of more or less than 10mCi.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to revise A9588 has not been approved. The requested revision does not improve the code. Existing code A9588 "Fluciclovine f-18, diagnostic, 1 millicurie" adequately describes the product that is the subject of this request and is it available for assignment by insurers if they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS' HCPCS workgroup for the opportunity to present. The speaker requested a change to the dose descriptor to "per study dose" instead of 1mCi. The speaker also provided the following examples for the revised descriptor to improve the code: 1) be consistent with other PET pharmaceuticals; 2) reduce confusion amongst MACs and providers regarding billing; and 3) ensure hospitals are reimbursed appropriately.

FINAL DECISION:

This request to revise A9588 has not been approved. The requested revision does not improve the code. Existing code A9588 "Fluciclovine f-18, diagnostic, 1 millicurie" adequately describes the product that is the subject of this request and it is available for assignment by insurers if they deem appropriate.

Tuesday, May 16, 2017

Agenda Item # 5

Application# 17.033

TOPIC

Request to establish a new Level II HCPCS code to identify aminolevulinic acid hydrochloride, Trade Name: Ameluz.

Applicant's suggested language: "Ameluz (aminolevulinic acid hydrochloride) gel, 10%, for topical use".

BACKGROUND

Biofrontera, Inc., submitted a request to establish a new HCPCS code to identify AMELUZ. According to the applicant, AMELUZ is an antineoplastic agent, Ameluz (5-aminolevulinic acid hydrochloride) for topical use for lesion-directed and field-directed photodynamic therapy (PDT) of actinic keratosis of mild to moderate intensity on the face and scalp.

.AMELUZ is administered topically. Gel should be applied approximately 1mm thick and include approximately 5mm of the surrounding skin. The application area should not exceed 20cm2 and no more than 2 grams of AMELUZ (one tube). It is supplied in a 2 gram tube.

The applicant comments that there are no current HCPCS codes that describe AMELUZ and that there is a precedent for creating separate HCPCS codes for drugs used with PDT to treat Actinic Keratoses.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Aminolevulinic Acid HCL For Topical Administration, 10%, 1 mg". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked the CMS" workgroup and expressed agreement with the preliminary recommendation to establish a new code. However, the speaker stated disagreement with the dose descriptor assigned to the code since it only comes in 2 gram tube. The speaker reiterated the original request for the description to read as follows: "Aminolevulinic acid HCI gel 10% for topical administration 2 gram tube, instead of "Aminolevulinic acid HCL 10% for topical administration."

FINAL DECISION:

Establish J7345, "Aminolevulinic Acid HCL For Topical Administration 10% gel, 10 mg".

Tuesday, May 16, 2017

Agenda Item # 6

Application# 17.007

TOPIC

Request to establish a new HCPCS Level II code to identify a levonorgestrel-releasing intrauterine system, 19.5 mg. Trade Name: Kyleena

Applicant's suggested language: "JXXXX: levonorgestrel-releasing intrauterine contraceptive system (Kyleena), 19.5".

BACKGROUND

Bayer Healthcare Pharmaceuticals, Inc., describes Kyleena, a levonorgestrel-releasing intrauterine system, 19.5 mg as an intrauterine contraceptive device indicated to prevent pregnancy for up to five years in nulliparous and parous women.

Kyleena contains 19.5 mg of levonorgestrel and prevents pregnancy for up to 5 years.

The local mechanism by which continuously released levonorgestrel contributes to contraceptive effectiveness of Kyleena has not been conclusively demonstrated. Kyleena is supplied in a carton of one sterile unit, which includes one Kyleena contained within an inserter. Kyleena consist of a T-shaped polyethylene frame (T-body) with a steroid reservoir (hormone elastomer core) containing 19.5 mg of levonorgestrel around the vertical stem. A ring composed of 99.5% pure silver is located at the top of the vertical stem close to the horizontal arms and is visible by ultrasound. The inserter, which is used for placement of Kyleena into the uterine cavity consists of a symmetric two-sided body and slider that are integrated with flange, lock, pre-bent insertion tube and plunger.

According to the applicant, Kyleena is similar to other IUDs manufactured by Bayer which include Mirena and Skyla. It is also similar to Liletta manufactured by Allergan. Each of these IUDs differ significantly in indication, dosage, and duration of use. Differentiation of the four products is needed in order to ensure appropriate identification and payment.

Kyleena is currently billed using existing code J3490. The applicant comments that there is no existing HCPCS code that adequately describes Kyleena since it contains 19.5 mg of levonorgestrel and prevents pregnancy for up to 5 years.

PRELIMINARY HCPCS CODING RECOMMENDATION

1) Establish Q9984 "Levonorgestrel-releasing Intrauterine Contraceptive System, (Kyleena), 19.5 mg". Effective 7/1/17.

2) Discontinue Q9984, Effective 12/31/17.

3) Establish JXXX, "Levonorgestrel-releasing Intrauterine Contraceptive System, (Kyleena), 19.5 mg". Effective 1/1/18.

New code Q9984 adequately describes Kyleena.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION:

1) Establish Q9984 "Levonorgestrel-releasing Intrauterine Contraceptive System, (Kyleena), 19.5 mg". Effective 7/1/17.

2) Discontinue Q9984, Effective 12/31/17.

3) Establish J7296, "Levonorgestrel-releasing Intrauterine Contraceptive System, (Kyleena), 19.5 mg". Effective 1/1/18.

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Agenda Item # 7

Application# 17.009

TOPIC

Request to establish a new HCPCS code to identify Hydroxyprogesterone Caproate Injection.

Applicant's suggested language "JXXXX - Hydroxyprogesterone Caproate Injection, USP 250mg/mL".

BACKGROUND

ANI Pharmaceuticals, Inc., requested a new Level II HCPCS J code to identify Hydroxyprogesterone Caproate Injection. According to the applicant, this drug is used to treat advanced adenocarcinoma of the uterine corpus; manage amenorrhea and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology; to test for endogenous estrogen production; and to produce secretory endometrium and desquamation.

Hydroxyprogesterone is a potent, long-acting, progestational steroid ester which transforms proliferative endothelium into secretory endothelium, induces mammary gland duct development, and inhibits the production and/or release of gonadotropic hormone; it also shows slight esotrogenci, androgenic, or corticoid effects as well, but should not be relied upon for these effects. In advanced adesnocarcinoma of the uterine corpus, Hydroxyprogesterone Caproate Injection in a dosage of 1,000 mg or more, one or more times each week, often induces regressive changes.

Hydroxyprogesterone caproate Injection USP is available in vials providing hydroxyprogesterone caproate with a potency of 2250 mg per mL. The product is available as multiple dose, 5 mL vials containing hydroxyprogesterone caproate 250 mg/mL.

The applicant comments that the existing reimbursement codes are for miscellaneous products and for a product that has a much higher cost than this requested product.

PRELIMINARY HCPCS CODING RECOMMENDATION

1) Establish Q9985, "Injection, Hydroxyprogesterone Caproate, Not Otherwise Specified, 10 mg". Effective 7/1/17.

2) Establish Q9986, "Injection, Hydroxyprogesterone Caproate, (Makena), 10 mg". Effective 7/1/17.

3) Discontinue Q9985. Effective 12/31/17.

4) Discontinue Q9986. Effective 12/31/17.

5) Establish JXXXX, "Injection, Hydroxyprogesterone Caproate, Not Otherwise Specified, 10 mg". Effective 1/1/18

6) Establish JXXXX, "Injection, Hydroxyprogesterone Caproate, (Makena), 10 mg". Effective 1/1/18.

7) Change Medicare coverage indicator for existing code J1725 to "i". Effective 7/1/17.

New code Q9985, "Injection, Hydroxyprogesterone Caproate, Not Otherwise Specified, 10 mg" adequately describes the product that is the subject of this request.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION:

1) Establish Q9985, "Injection, Hydroxyprogesterone Caproate, Not Otherwise Specified, 10 mg". Effective 7/1/17.

2) Establish Q9986, "Injection, Hydroxyprogesterone Caproate, (Makena), 10 mg". Effective 7/1/17.

3) Discontinue Q9985. Effective 12/31/17.

4) Discontinue Q9986. Effective 12/31/17.

5) Establish J1729, "Injection, Hydroxyprogesterone Caproate, Not Otherwise Specified, 10 mg". Effective 1/1/18.

6) Establish J1726, "Injection, Hydroxyprogesterone Caproate, (Makena), 10 mg". Effective 1/1/18.

7) Change Medicare coverage indicator for existing code J1725 to "i". Effective 7/1/17.

8) Discontinue J1725 effective 12/31/17.

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Agenda Item # 8

Application# 17.013

TOPIC

Request to establish a new Level II HCPCS code to identify Immune Globulin Subcutaneous (Human) 20% Solution, Trade Name: CUVITRU.

Applicant's suggested language: JXXXX "Injection, immune globulin (CUVITRU), 100 mg".

BACKGROUND

Shire Pharmaceuticals, Inc. submitted a request to establish a new Level II HCPCS code to identify Cuvitru. According to the applicant, Cuvitru [Immune Globulin Subcutaneous (human)] 20% Solution is a subcutaneous immunoglobulin (SCIG) replacement therapy for primary humoral immunodeficiency (PI) in adults and children 2 years of age and older. Cuvitru supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial and viral agents. Cuvitru also 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 role of these antibodies and the mechanisms of action on IgG in Cuvitru have not been fully elucidated.

The dose, dose frequency, and number of sites is individualized based on the patient's pharmacokinetic and clinical response. Cuvitru is supplied as a 200 mg/mL (20%) protein solution for subcutaneous infusion, and is available in 5 mL (1 gram protein); 10 mL (2 grams protein); 20 mL (4 grams protein); and 40 mL (8 grams protein) vials.

Suggested areas for subcutaneous infusion of Cuvitru are abdomen, thighs, upper arms, or lateral hip. Cuvitru may be infused into multiple infusion sites. Use up to 4 sites simultaneously. Infusion sites should be at least four inches apart, avoiding bony prominences. Rotate sites with each administration.

The applicant comments that Cuvitru is a newly approved biologic approved via a unique BLA and that no current Level II HCPCS code adequately describes Cuvitru.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, Immune Globulin (CUVITRU), 100 mg". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION:

Establish J1555, "Injection, Immune Globulin (CUVITRU), 100 mg".

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Agenda Item # 9

Application# 17.014

TOPIC

Request to establish a new Level II HCPCS code to identify bezlotoxumab; Trade name ZINPLAVA.

Applicant's recommended language: "JXXXX - Injection, bezlotoxumab, 10 mg".

BACKGROUND

Merck, and Co., submitted a request to establish a Level II HCPCS code to identify ZINPLAVA. According to the applicant, ZINPLAVA is a human monoclonal antibody that binds to Claustridium difficile toxin B and neutralizes its effects. ZINPLAVA is indicated for use to reduce Claustoridium Difficile Infection (CDI), recurrence in adults who are receiving antibacterial drug treatment for CDI and who are at high risk for CDI recurrence. It is not indicated for the treatment of the presenting episode of CDI and is not an antibacterial drug. ZINPLAVA should only be used in conjunction with CDI antibacterial treatment.

The recommended dose of ZINPLAVA is 10 mg/kg. It is administered as an intravenous infusion over 60 minutes as a single dose. ZINPLAVA is provided in a single-dose 50 mL vial that contains 1000 mg of bezlotoxumab in 40 mL of solution (25 mg/mL).

The applicant comments that there is no HCPCS codes that currently describes bezlotoxumab. Currently, bezlotoxumab is billed with an unspecified HCPCS code.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, Bezlotoxumab, 10 mg. Effective 1/1/18".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION:

Establish J0565, "Injection, Bezlotoxumab, 10 mg.

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Agenda Item # 10

Application# 17.023

TOPIC

Request to establish a new Level II HCPCS code to identify atezolizumab, Trade Name: TECENTRIQ.

Applicant's suggested language: “Injection, atezolizumab, 10 mg”

BACKGROUND

Genentech, Inc. submitted a request to establish a new Level II HCPCS code to identify TECENTRIQ. According to the applicant, TECENTRIQ is a humanized programmed death-ligand 1 (PD-L1) blocking antibody. TECENTRIQ is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of adjuvant treatment; or patients with metastatic non-small cell lung cancer who have disease progression during or following platinum-containing chemotherapy. TECENTRIQ binds to PD-L1 expressed on tumor cells and/or tumor-infiltrating immune cells and blocks interactions with the PD-1 and B7.1 receptors on T cells and antigen presenting cells. This releases the PD-L1/PD-1 mediated inhibition of the immune response, including the activation of the antitumor immune response without inducing antibody-dependent cell-mediated cytotoxicity (ADCC).

The recommended dose of TECENTRIQ is 1200 mg administered as an intravenous infusion over 60 minutes every 3 weeks until disease progression or unacceptable toxicity. TECENTRIQ is supplied as a single-use vial containing 1200 mg in 20 mL (60 mg/mL) for infusion.

The applicant comments that no existing code identifies TECENTRIQ.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, Atezolizumab, 10 mg". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION:

Establish J9022, "Injection, Atezolizumab, 10 mg".

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Agenda Item # 11

Application# 17.047

TOPIC

Request to establish a new level II HCPCS code to identify olaratumab injection for intravenous use, Trade Name: LARTRUVO.

Applicant's suggested language: J9XXX, "injection, olaratumab, 1mg".

BACKGROUND

Eli Lilly, LLC, submitted a request for LARTRUVO. According to the applicant, LARTRUVO is a recombinant human IgG1 monoclonal blocking antibody that binds specifically to human platelet-derived growth factor receptor alpha (PDGFR-a)[2]. It is used in combination with doxorubicin for the treatment of adult patients with soft tissue sarcoma (STS), with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery.

LARTRUVO is supplied in 500mg/50mL (10mg/mL) single-dose vials. The recommended dose for LARTRUVO is 15 mg/kg administered as an intravenous infusion over 60 minutes on Days 1 and 8 of each 21-day cycle until disease progression or unacceptable toxicity.

The applicant comments that no existing HCPCS codes describe LARTRUVO.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, Olaratumab, 10 mg". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. No comments were offered at CMS' HCPCS Public Meeting in response to our preliminary decision.

FINAL DECISION:

Establish J9285, "Injection, Olaratumab, 10 mg".

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Agenda Item # 12

Application# 17.028

TOPIC

Request to establish a new Level II HCPCS code to identify eteplirsen injection, Trade Name: EXONDYS 51™.

Applicant's suggested language: JXXXX, EXONDYS 51™ (eteplirsen) injection, for intravenous use, per 1 mg.

BACKGROUND

Sarepta Therapeutics, Inc. submitted a request to establish a new Level II HCPCS code to identify EXONDYS 51. According to the applicant, EXONDYS 51 is an antisense oligonucleotide for the treatment of Duchenne muscular dystrophy (DMD) in patients who have confirmed mutation of the DMD gene that is amenable to exon 51 skipping.

Eteplirsen is designed to bind to exon 51 of dystrophin pre-mRNA, resulting in exclusion of this exon during this exon mRNA processing in patients with genetic mutations that are amenable exon 51 skipping. Exon skipping is intended to allow for production of an internally truncated dystrophin protein.

The recommended dose of EXONDYS 51 is 30 mg/kg body weight administered as an IV infusion over 35-60 minutes, once weekly. Each milliliter of EXONDYS 51 contains 50 mg eteplirsen, 0.2 mg potassium phosphate monobasic, 8 mg sodium chloride, and 1.14 sodium phosphate dibasic, anhydrous, in water for injection. EXONDYS 51 injection is supplied in single-dose vials and the solution is clear and colorless, and may have some opalescence. It is available in single-dose vials contain 100 mg/2 mL (50 mg/mL) eteplirsen and single-dose vials containing 500 mg/10 mL (50 mg/mL) eteplirsen.

The applicant comments that no existing HCPCS J-codes describe EXONDYS 51.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, Eteplirsen, 10 mg". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION:

Establish J1428, "Injection, Eteplirsen, 10 mg".

Tuesday, May 16, 2017

Agenda Item # 13

Application# 17.043

TOPIC

Request to revise existing HCPCS code S1090.

Applicant's suggested language: Revise existing S code S1090, which currently reads, “Mometasone furoate sinus implant, 370 micrograms”, to instead be a J code and read, “Mometasone furoate sinus implant”.

BACKGROUND

Intersect ENT has requested a revision to existing code S1090. According to the applicant, PROPEL and PROPEL Mini (known collectively as PROPEL) to provide sustained release of mometasone furoate via a bio absorbable sinus implant. PROPEL is used in patients with chronic sinusitis to deliver steroids to the sinus mucosa and maintain sinus patency following endoscopic sinus surgery.

Currently, the most specific code for PROPEL is S1090, but S codes are not reportable to Medicare or many other payers. Medicare instructs separate outpatient hospital reporting of code C2625 (Stent, non-coronary, temporary, with delivery system) for PROPEL but this code cannot be billed by an ASC or physician office.

The applicant comments that transitioning S1090 to a J code would facilitate uniform billing for all payers and settings. In addition, changing the descriptor to "each implant" would conform to other drug implants and accommodate future dosage modifications.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code S1090 "Mometasone Furoate Sinus Implant, 370 Micrograms" adequately describes the product that is the subject of this request. Existing code C2625 "Stent, non-coronary, temporary, with delivery system" is available for use for procedures performed in HOPPS and ASC.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with the CMS' HCPCS preliminary decision not to grant a J code to Propel. The speaker indicated that "payers support the creation of a J code for uniform reporting to eliminate administrative burden and facilitate appropriate and consistent payment. In addition, coding for Propel would be consistent with codes given to other drug implants used in the office setting."

FINAL DECISION:

Existing codes S1090 "Mometasone Furoate Sinus Implant, 370 Micrograms" and C2625 "Stent, Non-Coronary Temporary, With Delivery System" adequately describe the products that are the subject of this request, and are available for assignment by insurers. For coding guidance contact the insurer in whose jurisdiction a claim would be filed.

Tuesday, May 16, 2017

Agenda Item # 14

Application# 17.024

TOPIC

Request to establish a new Level II HCPCS code to identify granisetron extended-release injection, for subcutaneous use; Trade Name: Sustol®.

Applicant's suggested language: JXXXX, "Injection, granisetron extended-release, for subcutaneous use (SUSTOL), 1 mg."

BACKGROUND

Heron Therapeutics, Inc. submitted a request to establish a new Level II HCPCS code to identify Sustol. According to the applicant, Sustol is a novel, extended-release polymer formulation of granisetron that, when administered subcutaneously, forms a depot that slowly releases granisetron in a consistent, predictable manner, maintaining therapeutic concentrations over a period of 5 days or more. Sustol extended-release injection is an extended-release serotonin-3(5-HT#) receptor antagonist indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of MEC or AC combination chemotherapy regimens.

The recommended dosage is 10 mg administered as a single subcutaneous injection at least 30 minutes before the start of MEC or AC combination chemotherapy on day 1. Sustol requires slow, sustained injection, which may take up to 20 to 30 seconds. Sustol should not be administered more frequently than once every 7 days. Use of Sustol with successive chemotherapy cycles for more than 6 months is not recommended.

Sustol, 10 mg granisetron/0.4mL, is supplied in a single-use, pre-filled syringe for subcutaneous injection. Each syringe contains 10 mg granisetron incorporated in an extended-release polymer formulation.

The applicant comments that a new code is warranted because no existing HCPCS J-codes specifically describe Sustol, which is the only extended-release injectable formulation of granisetron. Miscellaneous HCPCS codes J3490 and C9399 are inadequate because they do not permit the appropriate identification of an extended-release injectable formulation of granisetron.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, Granisetron, Extended-Release, 0.1 mg". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The speaker thanked CMS' HCPCS workgroup for granting SUSTOL a new Jcode and indicated agreement with the preliminary recommendation.

FINAL DECISION:

Establish J1627, "Injection, Granisetron, Extended-Release, 0.1 mg".

Tuesday, May 16, 2017

Agenda Item # 15

Application# 17.060

TOPIC

Request to establish a new Level II HCPCS code to identify avelumab, Trade Name: BAVENCIO.

Applicant's suggested language, "JXXXX, Injection, avelumab, 10 mg".

BACKGROUND

EMD Serono, Inc. submitted a request to establish a new Level II HCPCS code to identify BAVENCIO. According to the applicant BAVENCIO is a fully human monoclonal antibody directed against programmed death ligand 1 (PD-L1). BAVENCIO binds PD-L1 and blocks the interaction between PD-L1 and the programmed death 1 (PD-1) and B7.1 receptors. By inhibiting PD-L1 interactions, BAVENCIO enables the activation of T-cells and the adaptive immune system.

The recommended dose of BAVENCIO is 10mg/kg administered as an IV infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity. BAVENCIO Injection is a sterile, preservative-free, and clear, colorless to slightly yellow solution for intravenous infusion supplied as a single-dose vial of 200 mg/10mL (20 mg/mL), individually packaged in a carton.

The applicant comments that a new code is warranted because there are currently no permanent or temporary HCPCS codes that describe BAVENCIO. According to the applicant, a unique HCPCS code is needed to recognize the expected approval of BAVENCIO under a unique BLA and ensure appropriate payment under Section 1847A of the Social Security Act.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, Avelumab, 10 mg". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION:

Establish J9023, "Injection, Avelumab, 10 mg".