

CMS HCPCS Public Meeting

May 14, 2019

Agenda Item # 1

Application # 19.002

Request to establish a new Level II HCPCS code to identify epoetin alfa-epbx, Trade Name: Retacrit; for ESRD use.

Applicant's suggested language: "Injection, Epoetin Alfa-epbx, Biosimilar, (Retacrit), 100 Units (for ESRD use)".

Application # 19.003

Request to establish a new Level II HCPCS code to identify epoetin alfa-epbx, Trade name: Retacrit; for non-ESRD use.

Applicant's suggested language: "Injection, Epoetin alfa-epbx, Biosimilar, (Retacrit), 1000 units (for non-ESRD use)."

Application # 19.007

Request to establish a new Level II HCPCS code to identify filgrastim-aafi biosimilar, Trade Name: Nivestym.

Applicant's suggested language: "Injection, filgrastim-aafi (G-CSF), biosimilar, (Nivestym), 1 microgram."

Agenda Item # 2

Application # 19.006

Request to establish a new Level II HCPCS code to identify pegfilgratim-cbqv, biosimilar, Trade Name: Udenyca.

Applicant's suggested language: " Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg."

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Agenda Item # 3

Application # 19.039

Request to establish a new Level II HCPCS codes to identify an injectable drug indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for: on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes. Trade Name: Jivi.

Applicant's suggested language: JXXXX "antihemophilic factor (recombinant) PEGylated-aucl, Jivi, per IU."

Agenda Item # 4

Application # 19.066

Request to establish a new Level II HCPCS code to identify tagraxofusp-erzs, an injectable drug, Trade Name: Elzonris.

Applicant's suggested language: J9XXX "Elzonris (tagraxofusp-erzs)."

Agenda Item # 5

Application # 19.085

Request to establish a new Level II HCPCS code to identify romosozumab-aqqg, Trade Name: Evenity.

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

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Agenda Item # 6

Application # 19.093

Request to establish a new Level II HCPCS code to identify Calaspargase pegol-mknl, Trade Name: Asparlas.

Applicant's suggested language: "Calaspargase pegol-mknl; 3,750 units/5 mL (750 units/mL)."

Agenda Item # 7

Application # 19.096

Request to establish a new Level II HCPCS code to identify Emapalumab-lzsg. Trade Name: Gamifant™.

Applicant's suggested language: "Infusion, emapalumab-lzsg injection, for intravenous use, per 1 mg".

Agenda Item # 8

Application # 19.005

Request to establish a new Level II HCPCS code to identify Pegfilgrastim-jmdb, Trade Name: fulphilia.

Applicant's suggested language: "Injection, pegfilgrastim-jmdb, biosimilar, (fulphilia), 6 mg".

Application # 19.013

Request to establish a Level II HCPCS code to identify Revefenacin inhalation solution, Trade Name: Yupelri.

Applicant's suggested language: "QXXXX Revefenacin inhalation solution, fda-approved final product, noncompounded, administered through DME, unit-dose vial, 175 mcg."

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Agenda Item # 8

Application # 19.091

Request to establish a new Level II HCPCS code to identify trastuzumab-dkst, biosimilar, Trade Name: Ogivri.

Applicant's suggested language: "Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg."

Agenda Item # 9

Application # 19.012

Request to establish a new Level II HCPCS code to identify trastuzumab-dttb, Trade Name: Ontruzant.

Applicant's suggested language: "QXXXX Injection, Trastuzumab-dttb, Biosimilar (Ontruzant), 10 mg."

Agenda Item # 10

Application # 19.069

Request to establish a new Level II HCPCS code to identify trastuzumab and hyaluronidase-oyk. Trade name: Herceptin Hylecta

Applicant's suggested language for J-code "Subcutaneous Injection, trastuzumab and hyaluronidase, 10 mg."

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Agenda Item # 11

Application # 19.022

Teva Pharmaceuticals USA, Inc. submitted a request to establish a new HCPCS Level II code to identify fremanezumab-vfrm. Trade name: Ajoyvy.

Applicant's suggested language "Injection, fremanezumab-vfrm for subcutaneous use, per 225 mg."

Agenda Item # 11

Application # 19.025

Request to establish a new Level II HCPCS code to identify SYNOJOYNT (1% sodium hyaluronate).

Applicant's suggested language: "synojoynt inj., per dose Hyaluronan or derivative, synojoynt, for intra-articular injection, per dose."

Application # 19.043

Request to establish a new Level II HCPCS code to identify Herzuma trastuzumab-pkrb, Trade Name: Herzuma.

Applicant's suggested language: JXXXX "Injection, trastuzumab-pkrb, 10 mg."

Application # 19.044

Request to establish a new Level II HCPCS code to identify rituximab-abbs, an injectable drug. Trade Name: Truxima.

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

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Agenda Item # 12

Application # 19.027

Request to establish two new codes to identify AZEDRA (iobenguane I 131) injection, for intravenous use, indicated for treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. Trade name: Azedra.

Applicant's suggested language:

AXXXX: "I 131 iobenguane, dosimetric dose per 1 millicurie."

AXXXX: "I 131 iobenguane, therapeutic, per 1 millicurie."

Agenda Item # 13

Application # 19.011

Request to establish another Level II HCPCS code to identify gemcitabine in sodium chloride injection, Trade Name: Infugem.

Applicant's suggested language: J9XXX "Gemcitabine in sodium chloride, ready-to-administer IV, 100 mg."

Agenda Item # 14

Application # 19.018

Request to establish a new Level II HCPCS code to identify esketamine nasal spray. Trade Name: Spravato

Applicant's suggested language: JXXXX "Nasal spray, esketamine, 28mg."

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Application # 19.019

Request to establish a new Level II HCPCS code to identify abiraterone acetate. Trade name: Zytiga.

Applicants suggested language: "Zytiga, oral 250 mg."

Agenda Item # 14

Application # 19.058

Request to establish a new Level II HCPCS code to identify apatulamide, an oral drug. Trade Name: Erleada.

Applicant's suggested language: JXXXX "Apalutamide, oral, 60 mg."

Agenda Item # 15

Application # 19.057

Request to establish a new Level II HCPCS code to identify cemiplimab-rwlc, Trade Name: Libtayo cemeplimab-rwlc.

Applicant's suggested language: J9XXX "Injection, cemiplimab- rwlc, 1 mg."

Agenda Item # 16

Application # 19.060

Request to establish a new Level II HCPCS code to identify Bendamustine hydrochloride, Trade Name: Belrapzo.

Applicant's suggested language: J9XXX "Injection, bendamustine HCL (Belrapzo), per 1 mg."

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Agenda Item # 17

Application # 19.073

Request to establish a new Level II HCPCS code to identify Cablivi (Caplacizumab-yhdp), Trade Name: Cablivi.

Applicant's suggested language: J9XXX "Injection, caplacizumab-yhdp, 10 mg."

Agenda Item # 18

Application # 19.076

Request to establish a new Level II HCPCS code to identify an injectable folate analog, Trade Name: Khapzory.

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

Agenda Item # 19

Application # 19.079

Request to establish a new Level II HCPCS code to identify an anti-neoplastic agent and immunomodulatory in the form of a recombinant humanized monoclonal antibody that targets CC chemokine receptor 4 (CCR4)-expressing cells, Trade Name: Poteligeo.

Applicants suggested language: J9XXX "Injection, mogamulizumab-kpkc, 1 mg."

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Agenda Item # 20

Application # 19.001

Request to revise existing Level II HCPCS code Q2040, which currently reads:
"Tisagenlecleucel, up to 250 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion", to instead read: "Tisagenlecleucel, up to 200,000 to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion."

Agenda Item # 21

Application # 19.046

Request to establish a new Level II HCPCS code to identify moxetumomab pasudotox-tdfk,
Trade Name: Lumoxiti.

Applicant's suggested language: JXXXX "Injection, moxetumomab pasudotox-tdfk, 0.01 mg."

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Agenda Item # 1

Application # 19.002

TOPIC

Request to establish a new Level II HCPCS code to identify epoetin alfa-epbx, Trade Name: Retacrit; for ESRD use.

Applicant's suggested language: "Injection, Epoetin Alfa-epbx, Biosimilar, (Retacrit), 100 Units (for ESRD use)".

BACKGROUND

Request from Pfizer, Inc., to establish a new Level II HCPCS code to identify Retacrit for ESRD use. Retacrit is an erythropoiesis-stimulating agent (ESA), indicated for the treatment of anemia due to: Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis; Zidovudine in patients with HIV-infection, the effects to of concomitant myelosuppressive chemotherapy; and for reduction of allogenic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery.

PRELIMINARY HCPCS CODING RECOMMENDATION

Established new Level II HCPCS code Q5105 "Injection, Epoetin Alfa, Biosimilar, (Retacrit) (For ESRD on dialysis), 100 units", effective 7/1/2018.

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Agenda Item # 1

Application # 19.003

TOPIC

Request to establish a new Level II HCPCS code to identify epoetin alfa-epbx, Trade name: Retacrit; for non-ESRD use.

Applicant's suggested language: "Injection, Epoetin alfa-epbx, Biosimilar, (Retacrit), 1000 units (for non-ESRD use)."

BACKGROUND

Request from Pfizer, Inc., to establish a new Level II HCPCS code to identify Retacrit for non-ESRD use. Retacrit is an erythropoiesis-stimulating agent (ESA), indicated for the treatment of anemia due to: Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis; Zidovudine in patients with HIV-infection, the effects to of concomitant myelosuppressive chemotherapy; and for reduction of allogenic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code Q5106 "Injection, Epoetin Alfa, (Biosimilar), (Retacrit) (for non-ESRD use), 1000 Units", effective 7/1/2018.

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Agenda Item # 1

Application # 19.007

TOPIC

Request to establish a new Level II HCPCS code to identify filgrastim-aafi biosimilar, Trade Name: Nivestym.

Applicant's suggested language: "Injection, filgrastim-aafi (G-CSF), biosimilar, (Nivestym), 1 microgram."

BACKGROUND

Request from Pfizer, Inc., to establish a new Level II HCPCS code to identify Nivestym; a biosimilar to reference product Neupogen. Nivestym is a 175 amino acid human granulocyte colony-stimulating factor (G-CSF). It is FDA approved for use in patients with cancer receiving myelosuppressive chemotherapy; patients with Acute myeloid Leukemia receiving induction or consolidation chemotherapy; patients with cancer undergoing bone marrow transplantation; patients with severe chronic neutropenia; and for patients undergoing autologous peripheral blood progenitor cell collection and therapy.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS established new Level II HCPCS code Q5110 "Injection, Filgrastim-aafi, Biosimilar, (Nivestym), 1 microgram." New code Q5106 adequately describes the product that is the subject of this application, and is available for assignment by insurers.

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Agenda Item # 2

Application # 19.006

TOPIC

Request to establish a new Level II HCPCS code to identify pegfilgratim-cbqv, biosimilar, Trade Name: Udenyca.

Applicant's suggested language: " Injection, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5 mg."

BACKGROUND

Request from Coherus BioSciences, Inc., to establish a new Level II HCPCS code to identify Udenyca, a biosimilar to reference product Neulasta. Udenyca is a granulocyte colony-stimulating factor (G-CSF). It stimulates growth of neutrophils, a type of white blood cell important in the body's fight against infection. Udenyca is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS established new Level II HCPCS code Q5111 "Injection, Pegfilgrastim-cbqv, Biosimilar, (Udenyca), 0.5 mg", effective 1/1/2019. New code Q5111 adequately describes the product that is the subject of this application, and is available for assignment by insurers.

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Agenda Item # 3

Application # 19.039

TOPIC

Request to establish a new Level II HCPCS codes to identify an injectable drug proposed for the use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for: on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes. Trade Name: Jivi.

Applicants suggested language: JXXXX "antihemophilic factor (recombinant) PEGylated-aucl, Jivi, per IU."

BACKGROUND

Bayer HealthCare Pharmaceuticals Inc. submitted a request to establish a new code to identify Jivi, an injection for intravenous use. According to the applicant, Jivi, an antihemophilic factor (recombinant) PEGylated-aucl, is indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for: on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.

Jivi is administered via intravenous infusion after reconstitution. Dosing is based on patient weight and indication. There are different formulas for calculating dose.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code J7208 Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.". Effective 07/01/2019.

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Agenda Item # 4

Application # 19.066

TOPIC

Request to establish a new Level II HCPCS code to identify tagraxofusp-erzs, an injectable drug, Trade Name: Elzonris.

Applicant's suggested language: J9XXX "Elzonris (tagraxofusp-erzs)."

BACKGROUND

Stemline Therapeutics Inc. submitted a request to establish a new Level II HCPCS code to identify Elzonris (Tagraxofusp-erzs), an injection for intravenous (IV) infusion.

According to the applicant, Elzonris is a CD123-directed cytotoxin for the treatment of Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) in adults and pediatric patients 2 years and older.

Elzonris is administered by intravenous infusion at 12 mcg/kg over 15 minutes once daily on days 1-5 of 21-day cycle. The dosing period may be extended for dose delays up to day 10 of the cycle. The first administration cycle should occur in the inpatient setting. Subsequent cycles may be administered in the inpatient or appropriate outpatient setting.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code JXXXX "Injection, tagraxofusp-erzs, 10 micrograms"

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Agenda Item # 5

Application # 19.085

TOPIC

Request to establish a new Level II HCPCS code to identify romosozumab-aqqg, Trade Name: Evenity.

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

BACKGROUND

Amgen Inc., submitted a request to establish a new Level II HCPCS code to identify Evenity. Evenity is a sclerostin inhibitor indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Evenity is administered by subcutaneous injection and should be administered by healthcare provider. Two separate subcutaneous injections are needed to administer the total dose of 210 mg. Inject two syringes one after the other, once every month for twelve doses.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code JXXXX "Injection, romosozumab-aqqg, 1 mg."

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Agenda Item # 6

Application # 19.093

TOPIC

Request to establish a new Level II HCPCS code to identify Calaspargase pegol-mknl, Trade Name: Asparlas.

Applicant's suggested language: "Calaspargase pegol-mknl; 3,750 units/5 mL (750 units/mL)."

BACKGROUND

Servier Pharmaceuticals LLC, submitted a request to establish a new Level II HCPCS code to identify ASPARLAS. ASPARLAS is an asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regime for the treatment of acute lymphoblastic leukemia in pediatric and young adult patients' ages 1 month to 21 years. Recommended dosage is 2,500 units/m² intravenously no more frequently than every 21 days. It is supplied in a single dose vial 3,750 units/5ml (750 units/ml).

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code J9XXX "Injection, calaspargase pegol-mknl, 10 units."

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Agenda Item # 7

Application # 19.096

TOPIC

Request to establish a new Level II HCPCS code to identify Emapalumab-lzsg. Trade Name: Gamifant™.

Applicant's suggested language: "Infusion, emapalumab-lzsg injection, for intravenous use, per 1 mg".

BACKGROUND

Sobi, Inc., submitted a request to establish a new Level II HCPCS code to identify GAMIFANT. GAMIFANT is an interferon gamma blocking antibody indicated for the treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy. It is for intravenous infusion only. Recommended starting dose is 1 mg/kg as an intravenous infusion over 1 hour twice per week. Administer dexamethasone concomitantly with GAMIFANT.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code J92XX "Injection, emapalumab-lzsg, 1 mg".

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Agenda Item # 8

Application # 19.005

TOPIC

Request to establish a new Level II HCPCS code to identify Pegfilgrastim-jmdb, Trade Name: fulphilia.

Applicant's suggested language: "Injection, pegfilgrastim-jmdb, biosimilar, (filphilia), 6 mg".

BACKGROUND

Mylan GmbH submitted a request to establish a new Level II HCPCS code to identify a new biosimilar, Fulphilia (pegfilgrastim-jmdb). The reference product is Neulausta (pegfilgrastim). Fulphilia is a pegylated G-CSF that acts on hematopoietic cells by binding to specific cell surface receptors and thereby stimulates production of neutrophils and neutrophil precursors, a type of white blood cell important to the body's fight against infection. Fulphilia is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS established new Level II HCPCS code Q5108 "Injection, Pegfilgrastim-jmdb, Biosimilar, (fulphila), 0.5 mg." New code Q5108 adequately describes the product that is the subject of this request and is available for assignment by insurers.

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Agenda Item # 8

Application # 19.013

TOPIC

Request to establish a Level II HCPCS code to identify Revefenacin inhalation solution, Trade Name: Yupelri.

Applicant's suggested language: "QXXXX Revefenacin inhalation solution, fda-approved final product, noncompounded, administered through DME, unit-dose vial, 175 mcg."

BACKGROUND

Mylan Specialty L.P., submitted a request to establish a new Level II HCPCS code to identify Yupelri (revfenacin) Inhalation Solution.

Yupelri inhalation solution is an anticholinergic long-acting muscarinic antagonist indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Yupelri is for oral inhalation use only. It is supplied in a unit-dose vials for nebulization. One 175 mcg vial (3 mL) once daily. For use with a standard jet nebulizer with a mouthpiece connected to an air compressor.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code J7677 "Revefenacin Inhalation Solution, FDA-approved final product, non-compounded, administered through DME, 1 microgram". Effective 7/1/2019.

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Agenda Item # 8

Application # 19.091

TOPIC

Request to establish a new Level II HCPCS code to identify trastuzumab-dkst, biosimilar, Trade Name: Ogivri.

Applicant's suggested language: "Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg."

BACKGROUND

Mylan GmbH, submitted a request to establish a Level II HCPCS code to identify Ogivri, a biosimilar to reference product Herceptin. Ogivri is a HER2/neu receptor antagonist indicated for the treatment of HER2-overexpressing breast cancer, HER-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. Ogivri is for intravenous (IV) infusion only.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new level II HCPCS code Q5114 "Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg", effective 7/1/2019. New code Q5114 will adequately describe Ogivri.

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Agenda Item # 9

Application # 19.012

TOPIC

Request to establish a new Level II HCPCS code to identify trastuzumab-dttb, Trade Name: Ontruzant.

Applicant's suggested language: "QXXXX Injection, Trastuzumab-dttb, Biosimilar (Ontruzant), 10 mg."

BACKGROUND

Merck Sharp & Dohme Corp., submitted a request on behalf of Samsung Bioepis Co., Ltd., to establish a new Level II HCPCS scode to identify Ontruzant.

Ontruzant for intravenous (IV) infusion is a HER2/neu receptor agonist, biosimilar to reference product Herceptin, indicated for: Adjuvant Breast Cancer: Adjuvant treatment of HER2-Overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer: as part of a treatment regime consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, as part of a treatment regime with docetaxel and carboplatin, and as a single agent following multi-modality anthracycline based therapy. Metastatic Breast Cancer: In combination with paclitaxel for the first-line treatment of HER2-Overexpressing metastatic breast cancer, and as a single agent treatment of HER2-Overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease. Metastatic Gastric Cancer: In combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2-Overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease.

PRELIMINARY HCPCS CODING RECOMMENDATION

- 1) Revise existing Level II HCPCS code J9355 which currently reads: "Injection, trastuzumab, 10 mg", to instead read : "Injection, Trastuzumab, Excludes Biosimilar, 10 mg", effective 7/1/2019;
- 2) Establish new Level II HCPCS code Q5112 "Injection, Trastuzumab-dttb, Biosimilar, (Ontruzant), 10 mg", effective 7/1/2019. New code Q5112 will adequately describe Ontruzant.

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Agenda Item # 10

Application # 19.069

TOPIC

Request to establish a new Level II HCPCS code to identify trastuzumab and hyaluronidase-oysk. Trade name: Herceptin Hylecta.

Applicant's suggested language for J-code "Subcutaneous Injection, trastuzumab and hyaluronidase, 10 mg."

BACKGROUND

Genentech, Inc. submitted a request to establish a new Level II HCPCS code to identify Herceptin Hylecta (a combination of Trastuzumab and Hyaluronidase-oysk), injection for subcutaneous use.

According to the applicant, Herceptin Hylecta is indicated for the treatment of adult patients with Adjuvant Breast Cancer and Metastatic Breast Cancer. For metastatic breast cancer, it is used in combination with paclitaxel for first-line treatment.

The recommended dose of Herceptin Hylecta is 600 mg trastuzumab and 10,000 Units hyaluronidase human (120 mg/2,000 Units per ml), administered subcutaneously every 3 weeks.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code J9356 "Injection, trastuzumab, 10 mg and hyaluronidase-oysk", effective 7/1/2019.

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Agenda Item # 11

Application # 19.022

TOPIC

Teva Pharmaceuticals USA, Inc. submitted a request to establish a new HCPCS Level II code to identify fremanezumab-vfrm. Trade name: Ajoovy.

Applicant's suggested language "Injection, fremanezumab-vfrm for subcutaneous use, per 225 mg."

BACKGROUND

Teva Pharmaceuticals USA, Inc. submitted a request to establish a new Level II HCPCS code to identify Ajoovy (fremanezumab-vfrm).

Ajoovy is a monoclonal antibody that selectively targets the calcitonin gene-related peptide (CGRP) ligand. It is indicated for the preventive treatment of migraine in adults.

Ajoovy is supplied as a sterile solution in a 225 mg/1.5 mL single-dose prefilled syringe for subcutaneous administration.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code JXXXX "Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)."

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Agenda Item # 11

Application # 19.025

TOPIC

Request to establish a new Level II HCPCS code to identify SYNOJOYNT (1% sodium hyaluronate).

Applicant's suggested language: "synojoynt inj., per dose Hyaluronan or derivative, synojoynt, for intra-articular injection, per dose."

BACKGROUND

Teva Pharmaceuticals USA, Inc. submitted a request to establish a new Level II HCPCS code to identify SYNOJOYNT (1% sodium hyaluronate).

According to the applicant, synojoynt is a sterile, viscoelastic solution of hyaluronate in a buffered physiological sodium chloride.

This device is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g. acetaminophen). SYNOJOYNT is a single administration preparation and should be injected into the knee joint in a series of intra-articular injections one week apart for a total of 3 injections. Dosage is 20 mg/2 ml per injection.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code JXXXX "Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg."

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Agenda Item # 11

Application # 19.043

TOPIC

Request to establish a new Level II HCPCS code to identify Herzuma trastuzumab-pkrb, Trade Name: Herzuma.

Applicant's suggested language: JXXXX "Injection, trastuzumab-pkrb, 10 mg."

BACKGROUND

Teva Pharmaceuticals submitted a request to establish a new Level II HCPCS code to identify Herzuma, an injection for intravenous use. According to the applicant, Herzuma is indicated for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer and for treatment of metastatic breast cancer.

Herzuma is not to be administered as an intravenous push or bolus. Herzuma is not to be mixed with other drugs. For adjuvant treatment of breast cancer, Herzuma is to be administered according to the following dose and schedule for a total of 52 weeks of Herzuma therapy: during and following paclitaxel, docetaxel, or docetaxel and carboplatin: initial dose of 4 mg/kg as an intravenous infusion over 90 minutes then at 2 mg/kg as an intravenous infusion over 30 minutes weekly during chemotherapy for the first 12 weeks (paclitaxel or docetaxel) or 18 weeks (docetaxel and carboplatin). One week following the last weekly dose of Herzuma, administer Herzuma at 6 mg/kg as an intravenous infusion over 30-90 minutes every three weeks. Extending adjuvant treatment beyond one year is not recommended. For metastatic treatment of breast cancer, administer Herzuma, alone or in combination with paclitaxel, at an initial dose of 4 mg/kg as a 90-minute intravenous infusion followed by subsequent once weekly doses of 2 mg/kg as 30-minute intravenous infusions until disease progression.

PRELIMINARY HCPCS CODING RECOMMENDATION

- 1) Revise existing Level II HCPCS code J9355 which currently reads: "Injection, trastuzumab, 10 mg" to instead read: "Injection, trastuzumab, excludes biosimilar, 10 mg", effective 7/1/2019
- 2) Establish new Level II HCPCS code Q5113 "Injection, trastuzumab-pkrb, biosimilar (Herzuma), 10 mg", effective 7/1/2019. Newly established code Q5113 will adequately describe Herzuma.

CMS HCPCS Public Meeting

May 14, 2019

Agenda Item # 11

Application # 19.044

TOPIC

Request to establish a new Level II HCPCS code to identify rituximab-abbs, an injectable drug.
Trade Name: Truxima.

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

BACKGROUND

Teva Pharmaceuticals submitted a request to establish a new Level II HCPCS code to identify Truxima, an injection for an intravenous use.

According to the applicant, Truxima is a CD20-directed cytolytic antibody indicated for the treatment of adult patients with Non-Hodgkin's Lymphoma (NHL); relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy; non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.

The recommended dose is 375 mg/m² as an intravenous infusion. The administration schedules of Truxima are based on indication.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code Q5115 "Injection, rituximab-abbs, biosimilar, (truxima), 10 mg". Effective 7/1/2019.

CMS HCPCS Public Meeting

May 14, 2019

Agenda Item # 12

Application # 19.027

TOPIC

Request to establish two new codes to identify AZEDRA (iobenguane I 131) injection, for intravenous use, proposed for treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. Trade name: Azedra.

Applicant's suggested language:

AXXXX: "I 131 iobenguane, dosimetric dose per 1 millicurie."

AXXXX: "I 131 iobenguane, therapeutic, per 1 millicurie."

BACKGROUND

Progccenics Pharmaceuticals, Inc. submitted a request to establish a new code to identify AZEDRA (iobenguane I 131) injection, for intravenous use.

AZEDRA (iobenguane I 131) injection is indicated for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy.

Administer AZEDRA intravenously as a dosimetric dose followed by two therapeutic doses administered 90 days apart. The recommended dosimetric dose is Patients greater than 50 kg: 185 to 222 MBq (5-6 mCi), Patients 50 kg or less: 3.7 MBq/kg (0.1 mCi/kg). The recommended therapeutic dose for each of the two doses is patients greater than 62.5 kg: 18,500 MBq (500 mCi), Patients 62.5 kg or less: 296 MBq/KG (8 mCi/kg). Adjust AZEDRA therapeutic doses based on radiation dose estimates results from dosimetry, if needed.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code A9XXX "Iodine I-131, iobenguane, 1 millicurie."

CMS HCPCS Public Meeting

May 14, 2019

Agenda Item # 13

Application # 19.011

TOPIC

Request to establish another Level II HCPCS code to identify gemcitabine in sodium chloride injection, Trade Name: Infugem.

Applicant's suggested language: " J9XXX Gemcitabine in soduim chloride, ready-to-administer IV, 100 mg."

BACKGROUND

Sun Pharmaceutical Industries Limited requested another Level II HCPCS code to identify Infugem (gemcitabine in 0.9% sodium chloride injection), 10mg/ml, for intravenous use.

According to the applicant, Infugem is a nucleoside metabolic inhibitor indicated: in combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy; in combination with paclitaxel, for first-line treatment of metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated; in combination with cisplatin for the treat of non-small cell cancer; and as a single agent for the treatment of pancreatic cancer.

Infugem (gemcitabine in 0.9% sodium chloride injection) is for intravenous infusion only. For ovarian cancer: 1000 mg/m² over 30 minutes on Days 1 and 8 of each 21- day cycle. Breast cancer: 1250 mg/m² over 30 minutes on Days 1 and 8 of each 21-day cycle. Non-small cell cancer: 1000 mg/m² over 30 minutes on Days 1, 8, and 15 of each 28-day cycle or 1250 mg/m² over 30 minutes on Days 1 and 8 of each 21-day cycle. Pancreatic cancer 1000 mg/m² over 30 minutes once weekly for the first 7 weeks, then one week rest, then weekly for 3 weeks of each 28-day cycle.

The applicant claims that a new, product specific code is necessary to identify Infugem based on a claim of a significant therapeutic distinction between Infugem and other gemcitabine products. Specifically, that Infugem is unique in that it is pre-mixed and ready-to-administer, whereas other gemcitabine products are not; and that use of the ready-to-administer product reduces cytotoxic exposure and dosing errors. The applicant also claims that Infugem is a single-source product because it has FDA NDA clearance, and as such, separate pricing is required under Medicare's ASP pricing program, which has previously been facilitated by establishing a separate code. The applicant added that once the product is marketed, miscellaneous codes would be used to identify it until a new code is created.

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Agenda Item # 13

Application # 19.011

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code J9201 "Injection, gemcitabine hydrochloride, 200 mg" adequately describes Infugem and is available for assignment by insurers. The NDA approval, by itself, does not establish Infugem as a sole source product. There are multiple gemcitabine 10 mg/ml products provided in single-use bags that are AP rated in the FDA orange book. And in that case, Infugem can be included in the same code; and is not subject to the separate pricing requirements under Medicare Part B ASP pricing program, as specified in section 1847A of the Social security Act. In addition, the notion of a significant therapeutic distinction is contradicted by the multiple AP ratings in the orange book.

CMS HCPCS Public Meeting

May 14, 2019

Agenda Item # 14

Application # 19.018

TOPIC

Request to establish a new Level II HCPCS code to identify esketamine nasal spray. Trade Name: Spravato

Applicants suggested language: JXXXX "Nasal spray, esketamine, 28mg."

BACKGROUND

Johnson & Johnson Health Care Systems Inc. submitted a request to establish a new Level II HCPCS code to identify Spravato (Esketamine).

Spravato is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for treatment-resistant depression (TRD) in adults.

Spravato nasal spray is supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. Each device delivers 2 sprays containing a total of 28 mg of esketamine. Spravato is a federally controlled substance because it can be abused or lead to dependence. The FDA has issued a black box warning for Spravato related to sedation; dissociation; abuse and misuse; and suicidal thoughts and behaviors. Spravato is administered only under a restricted Risk Evaluation and Mitigation Strategy (REMS) requiring patient enrollment, administration under the direct observation of a healthcare provider; and patients must be monitored by a healthcare provider for at least 2 hours after administration of Spravato.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS is delaying its preliminary code recommendation for Spravato pending further consideration.

CMS HCPCS Public Meeting

May 14, 2019

Agenda Item # 14

Application # 19.019

TOPIC

Request to establish a new Level II HCPCS code to identify abiraterone acetate. Trade name: Zytiga.

Applicants suggested language: "Zytiga, oral 250 mg."

BACKGROUND

Johnson & Johnson, Health Care Systems submitted a request to establish a new HCPCS Level II code to identify Zytiga (abiraterone acetate) tablets.

Zytiga is a CYP17 inhibitor indicated in combination with prednisone for the treatment of metastatic castration-resistant prostate cancer and metastatic high-risk castration-sensitive prostate cancer who received prior chemotherapy containing docetaxel.

The recommended dose for Zytiga is 1000 mg orally once daily with prednisone 5 mg orally once daily.

PRELIMINARY HCPCS CODING RECOMMENDATION

There is no need to establish another code to identify Zytiga because the drug would be reported using the appropriate, existing NDC code.

CMS HCPCS Public Meeting

May 14, 2019

Agenda Item # 14

Application # 19.058

TOPIC

Request to establish a new Level II HCPCS code to identify apatulamide, an oral drug. Trade Name: Erleada.

Applicant's suggested language: JXXXX "Apalutamide, oral, 60 mg."

BACKGROUND

Johnson & Johnson, Health Care Systems submitted a request to establish a new Level II HCPCS code to identify Erleada, an orally administered drug.

According to the applicant, Erleada is indicated for the treatment of patients with non-metastatic, castration-resistant prostate cancer (NM-CRPC).

The recommended dose of Erleada is 240 mg (four 60 mg tablets) administered orally once daily.

PRELIMINARY HCPCS CODING RECOMMENDATION

There is no need to establish another code to identify Erleada because the drug would be reported using the appropriate, existing NDC code.

CMS HCPCS Public Meeting

May 14, 2019

Agenda Item # 15

Application # 19.057

TOPIC

Request to establish a new Level II HCPCS code to identify cemiplimab-rwlc, Trade Name: Libtayo cemeplimab-rwlc.

Applicant's suggested language: J9XXX "Injection, cemiplimab- rwlc, 1 mg."

BACKGROUND

Regeneron submitted a request to establish a new Level II HCPCS code to identify Libtayo.

According to the applicant, Libtayo is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or patients with locally advanced CSCC who are not candidates for curative surgery or curative radiation.

The recommended dose for Libtayo is 350 mg, every 3 weeks, delivered during a 30-minute intravenous infusion until disease progression or unacceptable toxicity occur.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code J9XXX "Injection, cemiplimab-rwlc, 1 mg."

CMS HCPCS Public Meeting

May 14, 2019

Agenda Item # 16

Application # 19.060

TOPIC

Request to establish a new Level II HCPCS code to identify Bendamustine hydrochloride, Trade Name: Belrapzo.

Applicant's suggested language: J9XXX "Injection, bendamustine HCL (Belrapzo), per 1 mg."

BACKGROUND

Eagle Pharmaceuticals, Inc., submitted a request to establish a new Level II HCPCS code to identify Belrapzo (Bendamustine), an injection for intravenous use. According to the applicant, Belrapzo is indicated for the treatment of patients with Chronic Lymphocytic Leukemia (CLL) and the treatment of patients with indolent B-cell non-Hodgkin Lymphoma (NHL) that has progressed during or within six month of treatment with rituximab or a rituximab-containing regimen. The dosage for CLL is 100 mg/m² infused intravenously over 30 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. The dosage for NHL is 120 mg/m² infused intravenously over 60 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles. The volume needed for a required Belprazo dose is withdrawn from the multiple-dose vial aseptically and transferred to a 500 ml infusion bag containing 0.9% Sodium Chloride Injection, USP, or 2.5% Dextrose/ 0.45% Sodium Chloride Injection, USP.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code J9036 "Injection, bendamustine hydrochloride, (Belrapzo/Bendamustine), 1 mg", effective 7/1/2019

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Agenda Item # 17

Application # 19.073

TOPIC

Request to establish a new Level II HCPCS code to identify Cablivi (Caplacizumab-yhdp), Trade Name: Cablivi.

Applicant's suggested language: J9XXX "Injection, caplacizumab-yhdp, 10 mg."

BACKGROUND

Ablynx/Sanofi submitted a request to establish a new Level II HCPCVS code to identify Cablivi (Caplacizumab-yhdp), an intravenous injection.

According to the applicant, Cablivi is a von Willebrand factor (vWF)-directed antibody fragment indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

Cablivi should be administered immediately upon diagnosis of aTTP. The recommended dose is as follows: first day of treatment- 10 mg bolus intravenous injection after completion of plasma exchange on day 1. Susequent days of treatment during daily plasma exchange- 10 mg subcutaneous injection once daily following plasma exchange. Treatment after plasma exchange period- 10 mg subcutaneous injection once daily continuing for 30 days following the last daily plasma exchange.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS has not identified a claims processing need to establish another code to report caplacizumab-yhdp. For Medicare the product is self-administered at home and therefore, not reportable. To report use in HOPPS refer to code C9047 Injection, caplacizumab-yhdp, 1 mg. Then NDC code may also be used to report to non-Medicare insurers.

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Agenda Item # 18

Application # 19.076

TOPIC

Request to establish a new Level II HCPCS code to identify an injectable folate analog, Trade Name: Khapzory.

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

BACKGROUND

Spectrum Pharmaceuticals, Inc. submitted a request to establish a new Level II HCPCS code to identify Khapzory, an injection, for intravenous administration only.

According to the applicant, Khapzory is a folate analog indicated for 1) rescue after high-dose methotrexate therapy in patients with osteosarcoma; 2) diminishing the toxicity associated with the overdosage of folic acid antagonists or impaired methotrexate elimination; and 3) treatment of patients with metastatic colorectal cancer in combination with fluorouracil.

Recommended dosage for rescue after high-dose methotrexate therapy and for overdosage of folic acid antagonists or impaired methotrexate elimination is 7.5 mg (approximately 5 mg/m²) every six hours. Recommended dosage in combination with fluorouracil for metastatic colorectal cancer is Khapzory at 100 mg/m² over a minimum of 3 minutes, followed by fluorouracil at 370 mg/m², once daily for 5 consecutive days or Khapzory at 10 mg/m², followed by fluorouracil at 425 mg/m², once daily for 5 consecutive days.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing Level II HCPCS code J0641, which currently reads: "Injection, levoleucovorin calcium, 0.5 mg"; to instead read: "Injection, levoleucovorin, 0.5 mg". Multisource code J0641 as revised adequately describes Khapzory.

CMS HCPCS Public Meeting

May 14, 2019

Agenda Item # 19

Application # 19.079

TOPIC

Request to establish a new Level II HCPCS code to identify an anti-neoplastic agent and immunomodulatory in the form of a recombinant humanized monoclonal antibody that targets CC chemokine receptor 4 (CCR4)-expressing cells, Trade Name: Poteligeo.

Applicants suggested language: J9XXX "Injection, mogamulizumab-kpkc, 1 mg."

BACKGROUND

Kyowa Kirin, Inc. submitted a request to establish a new Level II HCPCS code to identify Poteligeo, an injection for intravenous infusion.

According to the applicant, Poteligeo is an anti-neoplastic agent and immunomodulatory in the form of a recombinant humanized monoclonal antibody that targets CC chemokine receptor 4 (CCR4)-expressing cells. Poteligeo is indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sezary syndrome (SS) after at least one prior systemic therapy. Both mycosis fungoides and Sezary syndrome are subtypes of cutaneous T-cell lymphoma, a rare Non-Hodgkin lymphoma.

The recommended dose of Poteligeo is 1 mg/kg administered as an intravenous infusion over at least 60 minutes. Administer weekly on days 1,8,15, and 22 of the first 28-day cycle, followed by infusion on days 1 and 15 of each subsequent 28-day cycle until disease progression or unacceptable toxicity.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code JXXXX "Injection, mogamulizumab-kpkc, 1 mg"

CMS HCPCS Public Meeting

May 14, 2019

Agenda Item # 20

Application # 19.001

TOPIC

Request to revise existing Level II HCPCS code Q2040, which currently reads: "Tisagenlecleucel, up to 250 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion", to instead read: "Tisagenlecleucel, up to 200,000 to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion."

BACKGROUND

Novartis Pharmaceuticals Corp., submitted a request to revise the dose descriptor of existing code Q2040 from "up to 250 million Car-positive viable T cells" to "200,000 to 600 million CAR-positive viable T cells", in order to accommodate the dosing range of a 2nd FDA-approved clinical indication on August 30, 2017. Kymriah utilizes autologous (patient derived) T cells genetically modified to express a chimeric antigen receptor (CAR) comprised of a murine single chain antibody fragment, which recognizes CD19 fused to intracellular signaling domains from 4-1BB (CD137) and CD3 zeta. The CD3 zeta component has been demonstrated to be involved with initiating T cell activation and antitumor activity while 4-LBB enhances the expansion and persistence of Kymriah. In vivo binding of the CAR allows targeted killing of malignant and non-malignant CD19 expressing tissue.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS discontinued existing code Q2040 "Tisagenlecleucel, up to 250 million car-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion", effective 1/1/2019; and established new code Q2042 "Tisagenlecleucel, up to 600 million car-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose", effective 1/1/2019. Newly established code Q2042 adequately describes Kymriah and accommodates FDA- approved dose ranges; and is available for assignment by insurers.

CMS HCPCS Public Meeting

May 14, 2019

Agenda Item # 21

Application # 19.046

TOPIC

Request to establish a new Level II HCPCS code to identify moxetumomab pasudotox-tdfk, Trade Name: Lumoxiti.

Applicant's suggested language: JXXXX "Injection, moxetumomab pasudotox-tdfk, 0.01 mg."

BACKGROUND

AstraZeneca Pharmaceuticals LP submitted a request to establish a new code to identify Lumoxiti, a drug for intravenous administration.

According to the applicant, Lumoxiti is a CD22-directed cytotoxin indicated for the treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA).

The recommended dose of Lumoxiti is 0.04 mg/kg administered as a 30-minute intravenous infusion on days 1, 3, and 5 of each 28-day cycle.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code JXXXX "Injection, moxetumomab pasudotox-tdfk, 0.01 mg"