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

Tuesday, May 15, 2018

This HCPCS Code Application Summary document includes a summary of each HCPCS code application discussed at the May 15, 2018 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' 2018-2019 HCPCS coding cycle.

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.

Tuesday, May 15, 2018

Agenda Item # 1

Application# 18.040

TOPIC

Request to establish a new Level II HCPCS code to identify an intraveneous penem antibacterial and beta lactamase inhibitor, Trade Name: Vabomere.

Applicant's suggested language: "Injection, meropenem and vaborbactam, 0.5 g/0.5 g."

BACKGROUND

The Medicine Company submitted a request to establish a new Level II HCPCS code to identify Vabomere (meropenem and vaborbactam). Vabomere, an intraveneous penem antibacterial and beta lactamase inhibitor is indicated for the treatment of patients 18 years and older with complicated urinary tract infections, including pyelonephritis, caused by designated susceptible bacteria.

The applicant comments that Vabomere is a combination of meropenem, an antibacterial, and vaborbactam, a novel, first-in-class beta-lactamase inhibitor that blocks certain types of resistance mechanisms used by bacteria. Vabomere has a two-part mechanism of action: (1) inhibition of certain bacterial enzymes by vaborbactam to protect meropenem, and (2) inhibition of bacterial cell wall synthesis by meropenem.

Vaborbactam protects meropenem from degradation by certain serine beta-lactamases such as Klebsiella pneumonia carbapenemase (KPC), an enzyme produced by certain carbapenem-resistant enterobacteriaceae (CRE). By inhibiting these beta-lactamase enzymes, Vabomere allows meropenem to be effective against bacterial infections that would otherwise be resistant and unresponsive to meropenam alone.

The recommended dosage of Vabomere is 4 grams (meropenem 2 grams and vaborbactam 2 grams) administered every 8 hours by intravenous (IV) infusion over 3 hours in patients greater than 18 years of age with an estimated glomerular filtration rate (eGFR) greater than 50 mL/min/1.73². Dosage adjustment is recommended in patients with renal impairment. Vabomere 2 grams is supplied as a sterile powder for constitution in single-dose glass vials containing 1 gram of meropenem (equivalent to 1.14 grams of meropenem trihydrate), 1 gram of vaborbactam, and 0.575 gram of sodium carbonate.

The applicant comments that a new code is warranted because no existing code encompasses both of Vabomere's active ingredients, meropenem and vaborbactam. In addition, distinct billing codes are necessary for antibiotic stewardship programs to accurately track and distinguish Vabomere use from other antibacterials, including meropenem-only products.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, meropenem and vaborbactam, 10mg/10mg." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS for their preliminary recommendation to establish a new J code to identify meropenem and vaborbactam for intravenous use and requested a 0.5g/0.5g dose descriptor "because this unit of measure is most aligned with the labeling and dosing of Vabomere" or an alternative 100 mg/100mg. The speaker also commented that CMS has previously approved codes for injection products with descriptions that include a fraction of a gram such as J0714 or J0295.

FINAL DECISION

Establish J2186, “Injection, meropenem and vaborbactam, 10mg/10mg, (20 mg).” Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 2

Application# 18.051

TOPIC

Request to establish a new Level II HCPCS code to identify infliximab-qbtx, Trade Name: IXIFI.

Applicant's suggested language: XXXXX-"Injection, infliximab, qbtx, biosimilar, 10 mg"

BACKGROUND

Pfizer, Inc., submitted a request to establish a new Level II HCPCS code to identify IXIFI. IXIFI, a biosimilar to REMICADE (infliximab), is a tumor necrosis factor (TNF) blocker. IXIFI is indicated for the treatment of Crohn's Disease, Pediatric Crohn's Disease, Ulcerative Colitis, Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, and Plaque Psoriasis. These conditions are associated with elevated concetrations of TNFα in involved tissues and fluids.

According to the applicant, Infliximab products neutralize the biological activity of TNF-alpha (TNFα) by binding with high affinity to the soluble and transmembrane forms of TNFα and inhibits binding of TNFα with its receptors. Infliximab products do not neutralize TNFB (lymphotoxin-α), a related cytokine that utilizes the same receptors as TNFα. Biological activities attributed to TNFα include: induction of acute phase reactants and other liver proteins, as well as tissue degrading enzymes produced by synoviocytes and/or chondrocytes. In Rheumatoid Arthritis, treatment with infliximab products reduced infiltration of inflammatory cells into inflamed areas of the joint as well as expression of molecules mediating cellular adhesion and vascular cell adhesion molecule -1, chemoattraction and tissue degradation. In Crohn's Disease, treatment reduced infiltration of inflammatory cells and TNFα production in inflamed areas of the intestines. In Psoriatic Arthritis, treatment resulted in a reduction of the number of T-cells and blood vessels in the synovium and psoriatic skin lesions as well as a reduction of macrophages in the synovium. In Plaque Psoriasis, treatment may reduce epidermal thickness and infiltration of inflammatory cells. The relationship between these pharmacodynamic activities and the mechanism(s) by which infliximab products exert their clinical effects is unknown.

The recommended dose of IXIFI is 5mg/kg given as an intravenous induction regimen at 0, 2, and 6 weeks followed by a maintenance regimen of 5mg/kg every 8 weeks thereafter, except for Ankylosing Spondylitis, which is every 6 weeks thereafter. Each 15 mL infusion is supplied as a single dose vial containing 100 mg of infliximab-qbtx lyophilized powder for intravenous infusion, following reconstitution with 10 mL of sterile water for injection. The applicant seeks a unique code to separately identify IXIFI from the reference product, REMICADE, and the infliximab biosimilars, Inflectra and Reneflexis, for the following reasons:

According to the applicant 1) the products “are not identical and may have minor differences in clinically inactive components”; 2) “a new, unique HCPCS code is needed to apply the Affordable Care Act-specified payment mechanism to biosimilar products”; and 3) “approved biosimilar products with a common reference product are no longer grouped into the same HCPCS code and should be assigned separate HCPCS codes.”

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q510X "Injection, Infliximab-qbtx, biosimilar, (ixifi), 10 mg" Effective 1/1/19.

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 recommendation.

FINAL DECISION

Establish Q5109 "Injection, Infliximab-qbtx, biosimilar, (ixifi), 10 mg" Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 3

Application# 18.028

TOPIC

Request to establish a new Level II HCPCS code to identify HEMLIBRA, with a descriptor that would allow for payment of an appropriate furnishing fee".

Applicant's suggested language: JXXXX-"Injection, emicizumab-kxwh, 20 mcg".

BACKGROUND

Genentech, Inc., submitted a request to establish a new Level II HCPCS code to identify HEMLIBRA, with a dose descriptor unit of 20 mcg to allow for billed units consistent with separate payment of an appropriate furnishing fee for items and services associated with furnishing of clotting factors. According to the applicant, HEMLIBRA is a bispecific factor IXa- and factor X-directed antibody that restores the function of missing activated factor VIII. Hemlibra functions as a factor VIII mimetic in its activity, and should be covered as a clotting factor VIII. Hemlibra is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors. HEMLIBRA supplied in single-dose vials containing emicizumab-kxwh at 30 mg/mL, 60 mg/0.4mL, 105 mg/0.7 mL, or 150 mg/kg. The recommended dose is 3 mg/mL by subcutaneous injection once weekly for the first 4 weeks, followed by 1.5 mg/kg once weekly.

The applicant comments that a new code is warranted for Hemlibra because it is a new molecular entity with a novel mechanism of action, not identified by existing codes. A new code would also assist in identification for the purposes of routine billing and claims submission.

PRELIMINARY HCPCS CODING RECOMMENDATION

Newly established code Q9995 "Injection, emicizumab-kxwh, 0.5 mg." Effective 7/1/18 is available for assignment by insurers, if they deem appropriate.

Discontinue Q9995 "Injection, emicizumab-kxwh, 0.5 mg." 12/31/18

Establish JXXXX-"Injection, emicizumab-kxwh, 0.5 mg." Effective 1/1/19. to replace Q9995 code

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker indicated support for the CMS' HCPCS preliminary recommendation to establish a new J code for "Injection, emicizumab-kxwh" effective 1/1/19 to replace Q9995. The speaker also suggested establishing the unit of 20mcg as an "appropriate furnishing fee' because otherwise it would have an impact on access and care.

FINAL DECISION

Establish Q9995 Injection, emicizumab-kxwh, 0.5 mg.

Discontinue Q9995 1/1/19 and crosswalk to J7170

Establish J7170 Injection, emicizumab-kxwh, 0.5mg eff 1/1/19

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Agenda Item # 4

Application# 18.052

TOPIC

Request to establish a new Level II HCPCS code to identify mometaseone furoate, Trade Name: SINUVA

Applicant's suggested language: JXXXX-"mometasone furoate, 1,350 mcg, sinus drug implant (Sinuva)."

BACKGROUND

Intersect ENT, Inc., submitted a request to establish a new Level II HCPCS code to identify a new sinus drug implant, SINUVA. According to the applicant, SINUVA is a new in-office drug treatment for recurrent nasal polyps. It is a physician-administered drug treatment for patients who have had previous ethmoid sinus surgery. This drug implant delivers 1,350 mcg of mometasone furoate directly to the ethmoid sinus.

SINUVA is a corticosteroid demonstrating anti-inflammatory activity. Corticosteroids have been shown to have a wide range of effects on multiple cells and mediators involved in inflammation.

One Sinuva Sinus Drug Implant contains 1,350 mcg of mometasone furoate, embedded in a bioabsorbable polymer matrix that provides for gradual release of the drug over 90 days. The SINUVA Sinus Drug Implant is administered intrasinally. It is supplied as single-use and is packaged in a foil pouch with a sterile disposable applicator.

The applicant comments that a new code is warranted because there is no existing HCPCS code to report mometasone furoate for recurrent polyps, and a code is needed to facilitate provider billing.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new code to identify SINUVA is not approved.SINUVA is an integral part ofan investigational procedure. As the CPT procedure code 0406T is investigational and has not yet been valued by the RUC, it is up to individual insurers to determine whether and how to pay, including whether the use of miscellaneous codes to identify Sinuva is appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation and requests reconsideration to establish a product-specific J code for Sinuva. The speaker also indicated that the AMA will delete 0406T at the end of this year. In addition, the speaker indicated that without

a new HCPCS code, SINUVA will be reported under J3490 since there is no unique code and this would create an administrative burden.

FINAL DECISION

Existing code J3490 "Unclassified drugs" is available for assignment by insurers, if they deem appropriate, to identify Sinuva, until such time as a specific procedure code is established and valued.

Tuesday, May 15, 2018

Agenda Item # 5

Application# 18.080

TOPIC

Request to revise existing Level II HCPCS code to identify Tildrakizumab, Trade Name: ILUMYA.

Applicant's suggested language: Jxxxx-"Tildrakizumab injection, 100 mg/mL."

BACKGROUND

Sun Pharmaceuticals, Inc., submitted a request to establish a new Level II HCPCS code to identify ILUMYA. According to the applicant, ILUMYA is indicated for the treatment of moderate-to-severe plaque psoriasis in patients who are candidates for systemic therapy or phototherapy. ILUMYA is a humanized IgGI/k monoclonal antibody that specifically binds to the p19 protein subunit of the IL-23 cytokine and inhibits its interaction with the IL-23 receptor. This action is thought to prevent a proximal step of the inflammatory disease pathway.

The recommended dose is 100 mg at weeks 0 and 4, and every 12 weeks thereafter. Patients weighing greater than 90 kg may benefit from a dose of 200 mg (two 100-mg injections). ILUMYA is administered by subcutaneous injection. ILUMYA is supplied in a carton of one 100 mg/mL single-dose prefilled syringe and 29-gauge fixed, ½ inch needle. The syringe contains 1 mL of 100 mg/mL Tildrakizumab.

The applicant comments that a new code is warranted because ILUMYA is a single source biological with a unique mechanism of action not adequately described by existing codes.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX- "Injection, tildrakizumab, 1 mg." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. Written comments were submitted indicating support for the preliminary recommendation issued by CMS and that the proposed new code would adequately describe ILUMYA.

FINAL DECISION

Establish J3245- "Injection, tildrakizumab, 1 mg." Effective 1/1/19

Tuesday, May 15, 2018

Agenda Item # 6

Application# 18.021

TOPIC

Request to establish either a single new Level II HCPCS code or alternatively, 2 separate codes, to identify a buprenorphine injection for subcutaneous use CIII, Trade Name: Sublocade

Applicant's suggested language: JXXXX Injection, buprenorphine extended-release, for subcutaneous use, per dose.

OR JXXXX Injection, buprenorphine extended-release, for subcutaneous use, less than or equal to 100 mg; and JXXXX Injection, buprenorphine extended-release, for subcutaneous use, greater than 100 mg

BACKGROUND

Indivior, Inc. submitted a request to establish either a single new Level II HCPCS code or, alternatively, 2 separate codes, to identify Sublocade. Sublocade is a new formulation of buprenorphine, a partial opioid agonist and is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product followed by dose adjustment for a minimum of 7 days. Sublocade should be used as a part of a complete treatment plan that includes counseling and psychosocial support.

The recommended dose of Sublocade is 2 monthly, initial doses of 300 mg, followed by a maintenance dose of 100 mg monthly. Sublocade is supplied as 100 mg/0.5 mL, and 300 mg/1.5 mL in a pre-filled syringe with a 19 gauge 5/8 inch needle. Prescription use of Sublocade is limited under the Drug Addiction Treatment Act. Sublocade should only be prepared and administered by a healthcare provider. It is administered only by subcutaneous injection in the abdominal region – serious harm or death could result if administered intravenously. Sublocade is only available through a restricted Sublocade Risk Evaluation and Mitigation Strategy (REMS) program; and may only be dispensed by a pharmacy certified in this REMS.

The applicant comments that a new code is necessary because no existing codes adequately describe Sublocade. The applicant further comments that a new code will ease administrative burden and a provider's risk of delayed or denied payment due to claims documentation.

PRELIMINARY HCPCS CODING RECOMMENDATION

Newly established codes Q9991"Injection, buprenophrine extended-release (sublocade), less than or equal to 100 mg." Effective 7/1/18.; and Q9992 "Injection, buprenophrine extended-release (sublocade), greater than 100 mg." Effective 7/1/18 are available for assignment by insurers if they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS and expressed agreement with the preliminary recommendation to maintain the new Q code for Sublocade.

FINAL DECISION

Newly established codes Q9991"Injection, buprenophrine extended-release (sublocade), less than or equal to 100 mg." Effective 7/1/18.; and Q9992 "Injection, buprenophrine extended-release (sublocade), greater than 100 mg." Effective 7/1/18 are available for assignment by insurers if they deem appropriate.

Tuesday, May 15, 2018

Agenda Item # 7

Application# 18.034

TOPIC

Request to establish a new Level II HCPCS code to identify ibalizumab-uiyk injection for intravenous use, Trade Name: TROGARZO.

Applicant's suggested language: Jxxxx-"Injection ibalizumab-uiyk, one (1) intravenous vial, 200mg.

BACKGROUND

THERAtechnologies, Inc., submitted a request to establish a new Level II HCPCS code to identify TROGARZO (ibalizumab-uiyk), an HIV-1 antiretroviral drug. TROGARZO, a CD4-directed post-attachment HIV-1 inhibitor, in combination with other antiretroviral(s) is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily-treatment experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen. According to the applicant, TROGARZO is one of several parenterally administered antiretroviral medications in development with the potential for infrequent dosing administrations.

TROGARZO is administered intravenously as a single loading dose of 2000 mg followed by a maintenance dose of 800 mg every 2 weeks after dilution of 250 mL of 0.9% sodium chloride injection, USP. TROGARZO is packaged in a single-use 2 mL vial containing 200mg/1.33mL (150 mg/mL) of balizumab-uiyk.

The applicant comments that a new code is warranted because existing code categories do not describe a long-acting, infused biologic antiretroviral (ARV), with the active ingredient ibalizumab-uiyk.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX-"Injection, ibalizumab-uiyk, 10 mg." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. Written comments were submitted by the applicant to support the establishment of a J code for the new antiretroviral treatment Trogarzo, that is the first intravenous long acting treatment for HIV-1.

FINAL DECISION

Establish J1746-"Injection, ibalizumab-uiyk, 10 mg." Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 8

Application# 18.053

TOPIC

Request to establish a new level II HCPCS code to identify Photrexa.

Applicant's suggested language: JXXXX – Riboflavin 5'-phosphate, 0.146% with or without dextran, ophthalmic solution, FDA-approved final product, non-compounded, up to two 3 mL syringes, single patient use.

BACKGROUND

Avedro, Inc., submitted a request to establish a new level II HCPCS code to identify Photrexa. According to the applicant, Photrexa is a photo-enhancing drug indicated for use with the KXL system in corneal collagen cross-linking (CXL) for the treatment of progressive keratoconus and corneal extasia following refractive surgery. It is administered as riboflavin 5'-phosphate ophthalmic solution (with dextran) and if needed riboflavin 5'-phosphate ophthalmic solution (with dextran). Recommended dosage is 1 drop Photrexa Viscous ((riboflavin 5'-phosphate in 20% dextran ophthalmic solution) 0.146% for topical ophthalmic use)) every 2 minutes for 30 minutes. If after 30 minutes, flare is not detected, instill 1 drop

Photrexa Viscous every 2 minutes for an additional 2 to 3 drops and recheck for flare. Repeat as necessary. Once flare is observed and ultrasound pachymetry is performed, if corneal thickness is less than 400 microns, instill 2 drops of Photrexa every 5 to 10 seconds until corneal thickness increases to at least 400 microns. Once the 400 micron threshold is met and flare is seen, the eye is irradiated as per instructions. During irradiation, continue typical instillation of Photrexa Viscous every 2 minutes for the 30-minute irradiated period. Photrexa Viscous is supplied in a 3 mL glass syringe containing sterile 1.56mg/mL riboflavin 5'-phosphate in 20% dextran ophthalmic solution. Photrexa (Without dextran) is supplied in a 3 mL glass syringe containing sterile 1.46 mg/mL riboflavin 5'-phosphate in 5' dextran ophthalmic solution.

The applicant comments that there are no existing HCPCS codes that describe this new drug, which is the only FDA-approved, non-compounded product with this chemical composition and FDA-approved/GMP-produced active ingredient. And because, "In creating CPT code 0402T in 2015, the CPT Editorial Panel did not consider Photrexa to be part of the service and expects the drug to be reported separately."

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX-"Riboflavin 5'-phosphate, opthalmic solution, up to 3 mL." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. Written comments were submitted in agreement with the CMS preliminary recommendation to establish a unique J code for Photrexa and request that this decision be finalized. The applicant also requested two proposed changes to the descriptor listed below:

1. change the base dose to "up to 6 mL," and 2. include the "non-compounded" in the descriptor.

FINAL DECISION

Establish J2787 "Riboflavin 5'-phosphate, ophthalmic solution, up to 3 mL." Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 9

Application# 18.035

TOPIC

Request to establish a new Level II HCPCS code to identify loxapine inhalation powder, for oral inhalation use, Trade Name: ADASUVE.

Applicant's suggested language: Jxxxx-"Loxapine, inhalation powder, 10mg".

BACKGROUND

Galen US Inc., submitted a request to establish a new Level II HCPCS code to identify ADASUVE. ADASUVE is a typical antipsychotic indicated for the acute treatment of agitation associated with Schizophrenia or bipolar I disorder in adults.

According to the applicant, ADASUVE provides rapid systemic delivery by inhalation of a thermally-generated aerosol of loxapine. Loxapine acts as an antagonist at central serotonin and dopamine receptors, with high affinity for serotine 5-HT2A and dopamine D1, D2, D3, and D4 receptors. Administration of ADASUVE results in rapid absorption of loxapine, with a median time of maximum plasma concentration (Tmax) of 2 minutes. The recommended dose is 10 mg administered by oral inhalation, using an inhaler. ADASUVE must be administered only by a healthcare professional. Administer only a single dose within any 24 hour period. After administration, monitor patients for signs and symptoms of bronchospasm at least every 15 minutes for at least 1 hour. ADASUVE is supplied as 10 mg inhalation powder in a single-use inhaler.

The applicant comments that a new code is warranted because existing codes are inadequate to describe ADASUVE.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Loxapine for inhalation, 1 mg." Effective 1/1/19.

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 preilimary recommendation.

FINAL DECISION

Establish J2062, "Loxapine for inhalation, 1 mg." Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 10

Application# 18.032

TOPIC

Request to establish a new Level II HCPCS code to identify guselkumab injection for subcutaneous use, Trade Name: TREMFYA.

Applicant's suggested language: JXXXX: "Injection, guselkumab, 100 mg/mL (single-dose prefilled syringe), for subcutaneous injection".

BACKGROUND

Johnson & Johnson, Health Care Systems, Inc., submitted a request to establish a new Level II HCPCS code to identify TREMFYA. According to the applicant, guselkumab is a human monoclonal IgG12 antibody that selectively binds to the p19 subunit of the leukin 23 (IL-23) and inhibits its interaction with the release of pro-inflammatory cytokines and chemokines. TREMFYA is indicated for treatment of adult patients with moderate-to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Guselkumab is available in a 100 mg/ML single-dose prefilled syringe. 100 mg is administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter.

The applicant comments that a new code is warranted because existing codes are inadequate to describe TREMFYA. In addition, as TREMFYA is a sole-source product, establishing a separate and distinct HCPCS code for TREMFYA is necessary for ASP reporting and more efficient payments.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, guselkumab, 1 mg." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. Written comments were submitted by the applicant to confirm that he agrees with CMS's preliminary recommendation regarding TREMFYA and expressed his appreciation for the customer focus and the careful work in the review of coding applications.

FINAL DECISION

Establish J1628, "Injection, guselkumab, 1 mg." Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 11

Application# 18.024

TOPIC

Request to establish a new level II HCPCS code to identify delafloxacin, a fluoroquinolone antibacterial drug. Trade Name: BAXDELA.

Applicant's suggested language: JXXXX-" Injection, delafloxacin, 300 mg".

BACKGROUND

Melinta Therapeutics, Inc., submitted a request for a new Level II HCPCS code to identify a fluoroquinolone antibacterial drug indicated for use in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. The antibacterial activity of BAXDELA, against gram –positive and gram-negative pathogens, is due to the inhibition of both bacterial topoisomerase IV and DNA gyrase (topoisomerase II) enzymes which are required for bacterial replication, transcription, repair and recombination.

BAXDELA for injection is administered by IV over 60 minutes, every 12 hours. It is supplied as a sterile, lyophilized powder in single-dose clear glass vials of 300 mg delafloxacin (equivalent to 433 mg delafloxacin meglumine). The 300-mg single-dose vials are packaged in cartons of 10. BAXDELA is also available in tablet form for oral administration, 450 mg every 12 hours for 5 to 14 days. The tablets contain 450 mg delafloxacin (equivalent to 649 mg delafloxacin meglumine), and are supplied in 20 count bottles or blister packs.

The applicant comments that no existing HCPCS codes specifically describe delafloxacin and hence, a code is necessary to identify and reimburse BAXDELA.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new code to separately identify Baxdela has not been approved. Itis inappropriate for inclusion in the HCPCS Level II code set based on reported and expected setting of use. Existing code C9462, Injection, delafloxacin, 1 mg, is available for assignment by insurers if deemed appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation not to issue a J-code for Baxdela.The applicant commented that CMS has issued a C-code for Baxdela but Medicare does not recognize this code except in the hospital outpatient setting. The primary speaker further added that without a specific J-code, access to Medicare beneficiaries to Baxdela will limit patient access to this option.

FINAL DECISION

This request to establish a new code to separately identify Baxdela has not been approved. It is inappropriate for inclusion in the HCPCS Level II code set based on reported and expected setting of use. Existing code C9462, Injection, delafloxacin, 1 mg, is available for assignment by insurers if deemed appropriate.

Tuesday, May 15, 2018

Agenda Item # 12

Application# 18.020

TOPIC

Request to establish a new Level II HCPCS code to identify the infliximab-abda, Trade Name: RENFLEXIS.

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

BACKGROUND

Merck Sharp & Dohme Corp., a subsidiary of Merck and Co., submitted a request to establish a new Level II HCPCS code to identify a biosimilar of infliximab (reference product trade name REMICADE). Infliximab, which is the active ingredient of RENFLEXIS, is a chimeric 1gG1κ monoclonal antibody specific for human tumor necrosis factor-alpha (TNFα). According to the applicant, the product uses human fibroblasts, endothelial cells, neutrophils, B and T lymphocytes, and epithelial cells to prevent TNFα from biding with its receptors. Infliximab also binds to the soluble and transmembrane forms of TNFα. This neutralizes the biological activity of TNFα.

The applicant claims that RENFLEXIS is indicated for reducing the signs and symptoms as well as maintaining the remission of pediatric and adult Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis, Ankylosing Spondylitis, Psoriatic Arthritis, and Rheumatoid Arthritis (with methotrexate. RENFLEXIS is administered by intravenous infusion over a period of two or more hours. The recommended dosages for each of these conditions (except Rheumatoid Arthritis), 5mg/kg at 0, 2, and 6 weeks, and then again every 8 weeks. Dosage for Rheumatoid Arthritis with methotrexate: 3 mg/kg at 0, 2, and 6 weeks, and then again every 8 weeks. Each single-dose, 20 mL vial contains 100 mg of infliximab.

The applicant comments that a new code is warranted because the current code Q5102 is shared and identifies all infliximab biosimilar products. There is no HCPCS code that specifically identifies RENFLEXIS.

PRELIMINARY HCPCS CODING RECOMMENDATION

Newly established code Q5104, "Injection, infliximab-abda, biosimilar (renflexis), 10 mg". Effective 4/1/18, is available for assignment by insurers, if they deem appropriate.

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 recommendation.

FINAL DECISION

Newly established code Q5104, "Injection, infliximab-abda, biosimilar (renflexis), 10 mg". Effective 4/1/18, is available for assignment by insurers, if they deem appropriate.

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Agenda Item # 13

Application# 18.073

TOPIC

Request to establish a new Level II HCPCS code to identify Lutetium lu 177 dotate, Trade Name: LUTATHERA

Applicant's suggested language: AXXXX-"Lutetium Lu 177, dotate, therapeutic, 200 millicuries."

BACKGROUND

Advanced Accelerator Applications, USA, Inc., submitted a request to establish a new Level II HCPCS code to identify LUTATHERA. Lutathera is a radiolabeled somatostatin analog indicated to treat adults for somatostatin receptor positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) including foregut, midgut, and hindgut neuroendocrine tumors.

The applicant comments that upon FDA approval, LUTATHERA will be the first therapeutic radiopharmaceutical using Lutetium 177 for intravenous infusion. Lu 177 DOTATATE has a high affinity for subtype 2 somatostatin receptors (ss2). It binds to malignant cells which overexpress sst2 receptors. With a maximum tissue penetration range of 2.2mm and a mean penetration range of 0.67mm, LUTATHERA is sufficient to kill targeted tumor cells with limited effect on neighboring normal cells.

The recommended treatment regimen consists of 4 administrations of 200 mCi (7.4 GBq) standard dose at a recommended interval of 8 weeks. LUTATHERA is supplied as a 370 mBq/mL single dose (10mCi/mL) vial.

The applicant comments that a new code is warranted because there is no existing code that adequately describes Lutetium 177.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish AXXXX, "Lutetium Lu 177, dotatate, therapeutic, 1 millicurie." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation and urged CMS to reconsider and change the HCPCS code descriptor to AXXXX "Lutetium lu 177, dotatate, therapeutic, 200 millicuries." The speaker indicated that using the current descriptor may lead to errors on the claims and unnecessary administrative burden.

FINAL DECISION

Establish A9513, “Lutetium Lu 177, dotatate, therapeutic, 1 millicurie.” Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 14

Application# 18.065

TOPIC

Request to establish a new Level II HCPCS code to identify (dexamethasone intraocular suspension), 9% for intraocular administration. Trade name: DEXYCU

Applicant's suggested language: XXXXX: “Dexamethasone intraocular suspension 9%, for intraocular administration, 0.005 mL”

BACKGROUND

Icon Bioscience, Inc., submitted a request to establish a new Level II HCPCS code to identify Dexycu. Dexycu is a corticosteroid indicated for the treatment of postoperative inflammation. Dexycu will be administered by cataract surgeons and ophthalmologists in ambulatory surgery centers and other outpatient surgical settings. Treatment consists of one intraocular injection 0.005 mL of 9% dexamethasone (equivalent to 517 micrograms), which, according to the package insert, is “administered into the posterior chamber inferiorly behind the iris at the end of ocular surgery”. According to the applicant, “Dexycu not a part of the actual ocular surgical procedure, which is complete cataract removal and placement of an intraocular lens in the capsular bag.”

Dexycu is supplied in a kit containing one 2mL vial filled with 0.5mL of 9% dexamethasone intraocular suspension, one 18-gauge needle, one 1mL plastic syringe, one 8mm cannula, and one syringe assembly pouch which contains a sterile ring and syringe guide. After preparation, 0.005 mL (103.4mg/mL) of dexamethasone will be administered.

The applicant comments that a new code is warranted because there are no identified codes for dexamethasone products that are 9% dexamethasone administered as a single 0.005 mL intraocular injection.

PRELIMINARY HCPCS CODING RECOMMENDATION

In the hospital inpatient setting, Dexycu, if used, is included in the DRG. For Medicare hospital outpatient use, J3490 and C9399 are available for assignment. Also, cataract procedures, specifically, CPT codes 66982, 66983, and 66984 are separately payable under the hospital OPPSS. Dexycu, if used, is currently packaged in the facility rate, and a request for separate identification of Dexycu for hospital outpatient should be made to CMS' pass-through application process. When the procedure is performed in a physician's office setting under the Physician Fee Schedule (PAFS), the facility rate applies, and there is no difference in pricing. CMS does not assign individual products to existing codes on behalf of insurers. Individual insurers have the necessary flexibility to assign codes to products as they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker commented that not to establish a "J" code creates a challenge when DEXYCU is used during an in-office procedure. The speaker urged CMS to grant a permanent HCPCS code to identify DEXYCU.

FINAL DECISION

Establish J1095 Injection, dexamethasone 9 percent, intraocular, 1 microgram. Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 15

Application# 18.074

TOPIC

Request to establish a new Level II HCPCS code to identify macimorelin 60 mg solution, Trade Name: MACRILEN

Applicant's suggested language: JXXXX-"MACRILEN (macimorelin 60 mg) for oral solution."

BACKGROUND

AErerna Zentaris, Inc., submitted a request to establish a new Level II HCPCS code to identify MACRILEN (macimorelin), an orally administered growth hormone secretagogue receptor (GHSR) agonist, indicated for the diagnosis of adult growth hormone deficiency (GHSG) antagonist, indicated for the diagnosis of adult growth hormone deficiency (AGHD). It stimulates growth hormone release by activating growth hormone secretagogue receptors (GHSR) mainly present in the pituitary and hypothalamus.

MACRILEN is prescribed by a healthcare professional and its solution should be prepared and administered by a healthcare professional. The dose must be calculated based on the patient's body weight. The recommended single oral dose is defined as 0.5 mg MACRILEN per kg body weight. The dose is administered as a reconstituted MACRILEN oral solution, after the patient has fasted for a minimum of 8 hours and must be used within 30 minutes after preparation. Venous blood samples for Growth Hormone determination are drawn at 30, 45, 60 and 90 minutes after administration.

MACRILEN is supplied in a single use aluminum pouch containing 60 macimorelin (equivalent to 68 mg of macimorelin acetate) that when reconstituted with 120 mL of water provides a 60 mg/120mL (0.5 mg/mL) macimorelin solution.

The applicant comments that a new code is warranted because there is no Level II HCPCS code for MACRILEN as it is a new drug approved by the FDA.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to identify MACRILIN has not been approved. MACRILIN is not suitable for coding in HCPCS Level II. CMS refers the applicant to the AMA for consideration of the appropriateness of CPT coding, as with other lab tests that include oral administration of drugs followed by serial blood draws.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation to not award a new HCPCS code for MACRILEN, a new evocative agent used in adult growth hormone stimulation testing (GGST). The speaker argued that MACRILEN is suitable for Level II HCPCS coding and that the AMA has already determined that evocative agents are not included in GHST and that the AMA is unlikely to award a new CPT code for MACRILEN that would include the cost of the drug.

FINAL DECISION

This request to establish a new Level II HCPCS code to identify MACRILIN has not been approved. MACRILIN is not suitable for coding in HCPCS Level II. CMS refers the applicant to the AMA for consideration of the appropriateness of CPT coding, as with other lab tests that include oral administration of drugs followed by serial blood draws.

Tuesday, May 15, 2018

Agenda Item # 16

Application# 18.033

TOPIC

Request to establish a new Level II HCPCS code to identify vestronidase alfa-vjbk, injection for intravenous use, Trade Name: MEPSEVII.

Applicant's suggested language: JXXXX- "MEPSEVII (vestronidase alfa-vjbk) injection, for intravenous use, 10 mg/5mL".

BACKGROUND

Ultragenyx Pharmaceutical Inc., submitted a request to establish a new Level II HCPCS code to identify the biologic MEPSEVII (vestronidase alfa-vjbk). According to the applicant, MEPSEVII (vestronidase alfa-vjbk) is intended to treat Mucopolysaccharidosis VII (MPS VII, Sly Syndrome), a lysosomal disorder characterized by the deficiency of glucuronidase (GUS) enzyme that results in glycosaminoglycans (GAGs) accumulation in cells throughout the body leading to multi-organ dysfunction, cognitive impairment, and reduced life expectancy. MEPSEVII is the first and only enzyme replacement therapy approved for patients with MPS VII.

MEPSEVII is a recombinant human lysosomal beta glucuronidase indicated in pediatric and adult patients for treatment of Mucopolysaccharidosis VII. MEPSEVII is intended to provide exogenous GUS enzyme for uptake in cellular lysomes. Mannose-6-phosphate (M6P) residues of the oligosaccharide chains allow binding of the enzyme, targeting to lysosomes and subsequent catabolism of accumulated GAGs in affected tissues. The recommended dosage of MEPSEVII is 4 mg/kg administered by intravenous infusion every two weeks under the supervision of a healthcare professional with the capacity to manage anaphylaxis. Premedication is recommended 30 to 60 minutes prior to the start of the infusion. MEPSEVII injection is a colorless to slightly yellow liquid supplied as a carton containing one 10 mg/5mL (2 mg/mL) single-dose vial (NDC 69794-001-01. MEPSEVII should be stored under refrigeration at 2 degrees C to 8 degree C (36 degrees F to 46 degrees F), protected from light, and not frozen or shaken.

Since MEPSEVII is not listed in any existing code, payers are using J-3490 or J-3590.

The applicant comments that a new code is warranted because there are no existing J-codes for MPS VII therapy and no other drugs are marketed under the same active ingredient as MEPSEVII.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX-"Injection, vestronidase alfa-vjbk, 1mg." Effective 1/1/19.

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 recommendation.

FINAL DECISION

Establish J3397 "Injection, vestronidase alfa-vjbk, 1mg." Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 17

Application# 18.042

TOPIC

Request to establish a new Level II HCPCS code to identify aprepitant, injectable emulsion, Trade Name: CINVANTI.

Applicant's suggested language: "JXXXX, aprepitant, injectable emulsion, per 10 mg."

BACKGROUND

Heron Therapeutics Inc., submitted a request to establish a new Level II HCPCS code to identify CINVANTI. The applicant is also requesting a temporary code for 2018, to avoid confusion when documenting CINVANTI. According to the applicant, CINVANTI is a P/neurolcinin NK_1 receptor antagonist indicated for use in adults in combination with other antiemetic agents for prevention of acute and delayed nausea and vomiting associated with initial and repeat doses of highly emetogenic cancer (HEC) therapy including high dose cisplatin with initial and repeat courses of moderately emetogenic cancer therapy (MEC).

CINVANTI is supplied in a carton containing a single-dose vial of 130 mg aprepitant/18 mL. The recommended HEC dosing is a single-dose regimen of 130 mg on Day 1 as an IV infusion over 30 minutes, approximately 30 minutes prior to chemotherapy. Recommended MEC dosing is a 3-day regimen, of 100 mg on Day 1 as an IV infusion followed by Aprepitant capsules (80 mg) given orally on Day 2 and Day 3. CINVANTI is part of a regimen that includes a corticosteroid and a 5-HT3 antagonist.

The applicant comments that a new code is warranted because there are no HCPCS codes that accurately describe CINVANTI. The applicant also notes that a new code will facilitate access to the treatment, ease administrative burden associated with miscellaneous coding, and allow payers to capture product-specific data.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, aprepitant, 1 mg." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION

Establish J0185, “Injection, aprepitant, 1 mg.” Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 18

Application# 18.043

TOPIC

Request to establish two new Level II HCPCS code to identify Acetylcysteine, Trade Name: Cetylev.

Applicant's suggested language: JXXXX" Cetylev (acetylcysteine) effervescent tablet for oral solution 500-mg tablet"; and

JXXXX" Cetylev (acetylcysteine) effervescent tablet for oral solution 2.5-g tablet."

BACKGROUND

Arbor Pharmaceuticals, LLC., submitted a request to establish two new Level II HCPCS codes; one each to identify different doses of Cetylev. According to the applicant, Cetylev effervescent tablet for oral solution are a prescription medicine used as an antidote to prevent or lessen liver damage in people who have taken too much or overdosed on acetaminophen. Acetaminophen doses of 150 mg/kg or greater have been associated with hepatotoxity. Acetaminophen probably protects the liver by maintaining or restoring the glutathione levels, or by acting as an alternative substrate for conjugation with, and thus detoxification of, the reactive metabolite of acetaminophen. Acetylcysteine has been shown to reduce the extent of liver injury following acetaminophen overdose.

Recommended dosing includes a Loading dose: 140 mg/kg and maintenance doses: 70 mg/kg repeated every 4 hours for a total of 17 doses. Cetylev is available in 500 mg and 2.5 effervescent tablet strengths for customized and accurate weight-based dosing. Cetylev effervescent tablets are simply dropped into water and quickly dissolved into an oral solution.

Cetylev is supplied in 1 carton of 20, 500-mg tablets (10 2-count blister packs) and 1 carton of 20, 2.5-g tablets (10 2-count blister packs).

The applicant comments that Cetylev was developed in response to the emergency medicine community's need for a different oral acetylcysteine treatment for acetaminophen overdose. It is currently listed as used in both hospital inpatient and outpatient facilities, as well as urgent care centers. In addition, a new code is warranted because the three existing J codes are for injection and inhalation through a nebulizer routes of administration, and as such do not adequately describe the oral form and functionality of Cetylev (Acetylcysteine).

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code has not been approved because it is not suitable for inclusion in the HCPCS Level II code set based on reported and expected setting of use.

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 recommendation.

FINAL DECISION

This request to establish a new Level II HCPCS code has not been approved. Cetylev is not suitable for inclusion in the HCPCS Level II code set based on reported and expected setting of use.

Tuesday, May 15, 2018

Agenda Item # 19

Application# 18.044

TOPIC

Request to establish a new Level II HCPCS code to identify hexaminolevulinate hydrochloride, trade name: CYSVIEW, when used for surveillance cystoscopy of bladder cancer with a flexible cystoscope.

Applicant's suggested language: JXXXX-"Injection hexaminolevulinate hydrochloride for intravesical instillation, 100 mg, for surveillance of bladder cancer with a blue light flexible cystoscope."

Additional request to modify existing Level II HCPCS code C9275 which currently reads: "Injection, hexaminolevulinate hydrochloride for intravesical instillation, 100 mg, per study dose", to instead read: "Injection hexaminolevulinate hydrochloride for intravesical instillation, 100 mg, for resection of bladder cancer with a blue light rigid cystoscope", in order to distinguish CYSVIEW when used for cystoscopy and resection of bladder cancer with a rigid cystoscope.

BACKGROUND

Photocure Inc., submitted a request to establish a new Level II HCPCS code and to revise existing code C9275 in a way that establishes a coding distinction between use of Cysview for different procedures. According to the applicant, CYSVIEW is used to perform Blue Light Cystoscopy (BLC) on patients suspected or known to have cancerous lesions of the bladder. Under blue light, CYSVIEW causes abnormal lesions of the bladder mucosa to fluoresce, demarcating them from normal background tissue, enabling their detection and/or removal.

The recommended dose for adults is 50mL of reconstituted solution containing 100 mg of CYSVIEW. CYSVIEW is instilled into the bladder (intravesical instillation) via a urinary catheter. It is supplied as a kit containing two vials (1) a 10mL vial containing 100mg powder of CYSVIEW for Intravesical Solution, and (2) a polypropylene vial containing 50 mL of diluent, and a Luer Lock catheter adapter.

The applicant comments that there is no unique, permanent code that adequately describes CYSVIEW. Currently, code C9274 is available for Medicare billing in the hospital outpatient setting when CYSVIEW is used with Blue Light Rigid Cystoscopy procedure for resection bladder cancer. This code is not accepted for use to identify CYSVIEW used with BLC in the physician's office setting. Separate codes will facilitate tracking and reimbursement.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish AXXXX-"Instillation, hexaminolevulinate hydrochloride, 100 mg." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation and indicated that CYSVIEW should be assigned a unique HCPCS drug code since it is a breakthrough drug for patients with bladder cancer. The speaker suggested that assigning a unique HCPS code to CYSVIEW will encourage physician office use which is more cost effective for the Medicare program. The speaker also requested that CMS consider issuing a temporary Q code for office use.

FINAL DECISION

Establish A9589 "Instillation, hexaminolevulinate hydrochloride, 100 mg." Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 20

Application# 18.045

TOPIC

Request to establish a new Level II HCPCS code to identify burosumab injection, for subcutaneous use. Trade Name: CRYSVITA.

Applicant's suggested language: Jxxxx-"CRYSVITA (burosumab-twza) injection, for subcutaneous use, 1 mL".

BACKGROUND

Ultragenyx Pharmaceutical, Inc., submitted a request to establish a new Level II HCPCS code to identify CRYSVITA. CRYSTIVA is a fibroblast growth factor 23 (FG-23) blocking antibody indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age or older.

According to the applicant, CRYSVITA is the first therapy approved for patients with XLH. For pediatric patients, the recommended starting dose regime is 0.8 mg/kg of body weight, administered every two weeks. For adults, the recommended dose regime is 1 mg/kg body weight, administered every four weeks. The minimum dose is 10 mg up to a maximum of 90 mg, for both pediatric and adult patients.

CRYSVITA is administered as a subcutaneous injection. It is supplied in 10 mg/mL, 20 mg/mL, and 30 mg/mL solutions for injection in single-dose vials.

According to the applicant, no existing HCPCS J-codes to describe CRYSVITA for XLH therapy.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX-"Injection, Burosumab-twza, 0.1 mg." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker expressed appreciation for CMS recommending a unique J-code for Crysvita. The speaker requested a change in the unit of measurement of 0.1 mg to 10 mg to facilitatea smooth claim and reimbursement process.

FINAL DECISION

Establish J0584 "Injection, Burosumab-twza,1 mg." Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 21

Application# 18.046

TOPIC

Request to establish a new Level II HCPCS code to identify voretigene neparvovec-rzyl for subretinal injection, Trade Name: LUXTURNA.

Applicant's suggested language: Jxxxx, "Injection, voretigene neparvovec-rzyl, per treatment dose."

BACKGROUND

Spark Therapeutics, Inc., submitted a request to establish a new Level II HCPCS code to identify LUXTURNA. LUXTURNA (voretigene neparvovec-rzyl) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy, an inherited progressive disease. Patients must have viable retinal cells as determined by the treating physician. According to the applicant, LUXTURNA is the first and only gene therapy product indicated for this indication.

According to the applicant, gene therapy is used to treat or prevent genetic diseases by seeking to augment, replace or suppress one or more mutated genes with functional copies. It addresses the root cause of an inherited disease by enabling the body to produce the protein or proteins necessary to restore health or to stop making a harmful protein or proteins, with the potential of bringing back function in the diseased cells and slowing disease progression. To deliver the functional gene into the cell, a vector is used to transport the desired gene and is delivered either intravenously or injected into specific tissue. The goal is to enable, through the one-time administration of gene therapy, a lasting therapeutic effect.

The recommended dose of LUXTURNA for each eye is 1.5 x 1011 vector genomes (vg) administered by subretinal injection in a total volume of 0.3 mL. LUXTURNA is supplied in a 0.5 mL extractable volume in a single-dos 2 mL vial for single administration in one eye. The supplied concentration ($5x10^{12}$vg/mL) requires a 1:10 dilution prior to administration. The diluent is supplied in two 2 mL vials.

The applicant comments that a new code is warranted because no existing HCPCS codes accurately describe voretigene neparvovec-rzyl.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX-"Injection, voretigene neparvovec-rzyl, 1 billion vector genomes." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker suggested a code descriptor of "Injection, voretigene neparvovec-rzyl, per vial" since it would be easier for providers and payers to use than a descriptor based on vector genomes. The speaker indicated that the FDA approved dosing is delivered in a total of subretinal volume of 0.3 mL, administration is performed in each eye on separate days within a close interval and a fixed dose for single administration into one eye, is supplied in a single-dose vial.

FINAL DECISION

Establish J3398 Injection, voretigene neparvovec-rzyl, 1 billion vector genomes. Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 22

Application# 18.047

TOPIC

Request to establish a series of 3 Level II HCPCS codes to identify and distinguish human rabies immunoglobulin (HRIG) products:

1) Request to establish a new code to identify human rabies immunoglobulin (HRIG) for intramuscular injection, Trade Name: KEDRAB. Applicant's suggested language: JXXX1-"Injection, rabies immune globulin (KEDRAB), 150 i.u."

2) Request to establish a code to identify HyperRAB S/D. Applicant's suggested language: JXXX2--"Injection, rabies immune globulin (HyperRAB S/D), 150 i.u."

3) Request to establish a code to identify Imogam Rabies – HT. Applicant's suggested language: JXXX3--"Injection, rabies immune globulin (Imogam Rabies-HT), 150 i.u."

BACKGROUND

Kedrion Biopharma, Inc., submitted a request to establish 3 new Level II HCPCS codes to identify and distinguish human rabies immunoglobulin (HRIG) products.

According to the applicant, "there is a question as to when CPT code 90375 or 90376 should be used for which immune globulin product. Clarification has been requested from the AMA CPT editorial panel but has been unable to provide guidance. It is for these reasons that the applicant is requesting a HCPCS Level II code".

The applicant comments that a new code is warranted to establish specific HCPCS J codes with brand names in the descriptor to allow for appropriate identification and payment of rabies immune globulin products.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code has not been approved. KEDRAB is not suitable for inclusion in the Level II code set. CMS refers the applicant tothe American Medical Association (AMA) for guidance relative to the CPT coding concerns expressed in the application.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS but disagreed with the preliminary coding recommendation and reiterated the request to establisha new HCPCScode to distinguish KEDRAM from other

human rabies immune globulin products. The speaker provided both a legal framework and precedence for their argument.

FINAL DECISION

This request to establish a series of new Level II HCPCS codes has not been approved. The taxonomy for HRIG products resides in the CPT coding system. CMS refers you to the American Medical Association (AMA) to resolve the CPT coding concerns expressed in your application.

Tuesday, May 15, 2018

Agenda Item # 23

Application# 18.048

TOPIC

Request to establish a new Level II HCPCS code to identify the human fibrinogen concentrate, Trade Name: FIBRYGA

Applicant's suggested language: JXXXX-"Injection human fibrinogen concentrate (FIBRYGA), per mg."

BACKGROUND

Octapharma USA, Inc., submitted a request to establish a new Level II HCPCS code to identify the biologic FIBRYGA. According to the applicant, FIBRYGA is a concentrate of fibrinogen (Factor 1), a soluble plasma protein that, during the coagulation process, is converted to fibrin, one of the key components of a blood clot.

FIBRYGA is indicated for the treatment of acute bleeding episodes in adults and adolescents with congenital fibrinogen deficiency, including afibrinogenemia, or complete absence of fibrinogen, and hypofibrinogenemia, or reduced plasma fibrinogen concentration. Absence or low levels of fibrinogen may cause life-threatening bleeding episodes or hemorrhage.

The product is supplied in a package with single-dose, single-use bottle lyophilized powder along with a diluent, sterile Water for Injection. Each bottle contains approximately 1 g of fibrinogen concentrate. The recommended target fibrinogen plasma level is 100 mg/dL for minor bleeding and 150 mg/dL for major bleeding. The patient's fibrinogen level should be monitored during treatment of FIBRYGA. Additional infusions of FIBRYGA should be administered if the plasma fibrinogen level is below the accepted lower limit (80 mg/dL for minor bleeding, 130 mg/dL for major bleeding) of the target level until hemostastis is achieved.

The dose should be individually calculated for each patient based on the target plasma fibrinogen level for the type of bleeding, actual measured plasma fibrinogen level, and body weight.

The recommended dose is 70 mg per kg of body weight administered intravenously.

The applicant comments that a new code is warranted because it would set payment for FIBRYGA based on ASP information for other products.

PRELIMINARY HCPCS CODING RECOMMENDATION

1. Establish JXXXX," Injection, Injection, human fibrinogen concentrate (FIBRYGA), 1 mg." Effective 1/1/19.

2. Revise existing code J7178,"Injection, human fibrinogen concentrate, 1 mg",to instead read, J7178 "Injection, human fibrinogen concentrate, not otherwise specified, 1 mg"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item. Written comments were submitted by the applicant agreeing with CMS and requested finalization of the preliminary recommendation.

FINAL DECISION

1. Establish J7177," Injection, human fibrinogen concentrate (FIBRYGA), 1 mg." Effective 1/1/19.

2. Revise existing code J7178,"Injection, human fibrinogen concentrate, 1 mg", to instead read, J7178 "Injection, human fibrinogen concentrate, not otherwise specified, 1 mg"

Tuesday, May 15, 2018

Agenda Item # 24

Application# 18.049

TOPIC

Request to establish a new Level II HCPCS code to identify Crotalidae Immune F (ab¹) (Equine), Trade Name: Anavip.

Applicant's suggested language: JXXXX-"Injection, Crotalidae Immune F (ab¹) (Equine), one vial."

BACKGROUND

Rare Disease Therapeutics, Inc., submitted a request to establish a new Level II HCPCS code to identify Anavip. Anavip Crotalidae Immune F (ab¹) (Equine), is an antivenin for North America rattlesnake envenomation. Anavip is a preparation of equine immunoglobulin a sterile, lyophilized, polyvalent preparation of equine immunoglobulin F (ab¹) fragments, manufactured from plasma of horses immunized with venon Bothrops asper and Crotalus durissus. Anavip binds and neutralize venom toxins, facilitating redistribution away from target tissues and elimination from the body.

Anavip is infused intravenously as a sterile lyophilized powder. Each vial contains not more than 120 milligrams (mg) total protein and not less than the indicated number of mouse LD50 neutralizing units: 780 LD 50 units for Bothrops asper and 790 LD 50 units of Crotalus durissus. The initial dose of Anavip is 10 vials, each of which is reconstituted with 10 milliliters (mL) of sterile normal saline, combined and further diluted to a total of 250 mL. Additional 10 vial doses may be required to achieve initial stabilization determined by arresting progression of symptoms. The amount of Anavip required to treat a snake bitten patient is highly variable owing in part to the venom burden, the potency of the venom and the time to presentation to a health care provider. There is no physician office use for this drug.

The applicant comments that a new code is warranted because existing codes do not adequately describe Anavip since it is equine-derived (not ovine) and contains F (ab¹)² product approved by the FDA..

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, crotalidae immune Fab (Equine), 120 mg." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS for the preliminary recommendation of a new J code for Anavip. The speaker asked that the preliminary recommendation be revised as follows:

"Injection, Crotalidae immune F (ab')2 (equine), 120 mg".

FINAL DECISION

Establish J0841, “Injection, crotalidae immune F(ab')2 (Equine), 120 mg.” Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 25

Application# 18.041

TOPIC

Request to establish a new Level II HCPCS code to identify 235 mg fosnetupitant/ 0.25 mg palonosetron for injection, Trade Name: AKYNZEO

Applicant's suggested language: JXXXX- "AKYNZEO, (fosnetupitant/palonosetron) for injection, 1 unit."

BACKGROUND

Helsinn Therapeutics, (US) Inc., submitted a request to establish a new Level II HCPCS code to identify AKYNZEO for injection.

The applicant comments that AKYNZEO is a single source drug injection that is a fixed combination antiemetic comprised of palonosetron and fosnetupitant (a pro-drug of netupitant). Netupitant is a selective antagonist of human substance P/neurokinin 1 (NK1) receptors. It is available as a single-administration, fixed-dose combination (FDC) IV injection.

AKYNZEO for injection is indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including but not limited to highly emetogenic chemotherapy.

The applicant comments that the rationale for using two antiemetics for emesis prevention is based on the pharmacology of each agent and duration of time needed to prevent emesis. The goal of emesis control in the cancer patient is the prevention of nausea and vomiting during an acute phase of risk and a delayed phase of risk.

The proposed dosages of AKYNZEO for injection in conjunction with dexamethasone in adults are one vial of AKYNZEO for injection; reconstituted in 50 mL of 5% Dextrose injection, USP or 0.9% sodium chloride injection, USP and administered over 30 minutes as an intraveneous infusion 30 minutes before chemotherapy. AKYNZEO for injection is supplied as 235 mg fosnetupitant/0.25 mg palonosetron lyophilized powder for reconstitution in single-dose vial.

The applicant comments that a new code is warranted because AKYNZEO (netupitant/ palonosetron) is a fixed dose combination with a different generic name, descriptor and dosage than any other approved antiemetic.

PRELIMINARY HCPCS CODING RECOMMENDATION

1. Establish JXXXX "Injection, fosnetupitant 235 mg and palonosetron 0.25 mg. Effective 1/1/19.

2. Revise existing code J8655 "Netupitant 300 mg and palonosetron 0.5 mg" to instead read "Netupitant 300 mg and palonosetron 0.5 mg, oral." Effective 1/1/19.

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 recommendation.

FINAL DECISION

1. Establish J1454 "Injection, fosnetupitant 235 mg and palonosetron 0.25 mg. Effective 1/1/19.

2. Revise existing code J8655 "Netupitant 300 mg and palonosetron 0.5 mg" to instead read "Netupitant 300 mg and palonosetron 0.5 mg, oral." Effective 1/1/19.

Tuesday, May 15, 2018

Agenda Item # 26

Application# 18.039

TOPIC

Request to establish a single new Level II HCPCS code to identify Feraheme (ferumoxytol) injection for intravenous (IV) use, to replace existing ferumoxytol codes Q0138 and Q0139, Trade Name: Feraheme

Applicant's suggested language: JXXXX, "Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg"; and

Discontinue the following 2 Level II Q codes: Q0138, Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-ESRD use)

Q0139, Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for ESRD on dialysis)

BACKGROUND

AMAG Pharmaceuticals Inc., submitted a request to establish a new Level II HCPCS code to identify Feraheme (ferumoxytol), which is indicated for the treatment of iron deficiency anemia (IDA) in adult patients with CKD. According to the applicant, Feraheme is a superparamagnetic iron oxide with a carbohydrate shell, which enters the reticuloendothelial system macrophages of the liver, spleen, and bone marrow. The iron is released for the iron-carbohydrate complex with vesicles of macrophages. Iron enters the intracellular storage iron pool or is transferred to plasma transferrin for transport to erythroid precursor cells for incorporation into hemoglobin. Feraheme has physiochemical properties that result in lower in free iron, isotonicity, and neutral pH. These properties may contribute to a convenient dosing and administration schedule.

The recommended dose of Feraheme is an initial 510 mg dose followed by a second 510 mg dose 3 to 8 days later. Administration is via an IV infusion in 50 to 200 mL 0.9% Sodium Chloride Injection or 55 Dextrose Injection over at least 15 minutes. The dosage is expressed in terms of mg of elemental iron, with each mL of Feraheme containing 30 mg of elemental iron.

Feraheme injection is an aqueous colloidal product that is formulated with mannitol. It is a liquid provided in single-use vials containing 510 mg of elemental iron. Each mL of the sterile colloidal solution of Feraheme injection contains 30 mg of elemental iron and 44 mg of mannitol and has low bleomycin-detectable iron.

According to the applicant, a "J" code is needed because not all insurers recognize "Q" codes. In addition, replacing the existing "Q" codes with a new unique HCPCS permanent J-code will simplify coding and claims adjudication. The applicant also comments that a new code is

warranted because there are no drugs that are marketed under the same ingredient category/generic name as Feraheme (ferumoxytol).

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to replace existing codes Q0138 and Q0139 with a new, less specific code to identify ferumoxytol is not approved. The proposed coding action does not improve the code set, because the proposed new code lacks the specificity needed to accurately process claims.

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 recommendation.

FINAL DECISION

This request to replace existing codes Q0138 and Q0139 with a new, less specific code to identify ferumoxytol is not approved. The proposed coding action does not improve the code set, because the proposed new code lacks the specificity needed to accurately process claims.

Tuesday, May 15, 2018

Agenda Item # 27

Application# 18.055

TOPIC

Request to establish a new Level II HCPCS code to identify dantrolene sodium for injectable suspension, for intravenous use, Trade Name: RYANODEX.

Applicant's suggested language: JXXXX-"Injection, dantrolene sodium (ryanodex), low-volume high-concentration suspension, per 1 mg."

BACKGROUND

Eagle Pharmaceuticals, Inc., submitted a request to establish a new Level II HCPCS code to identify RYANODEX. According to the applicant, RYANODEX is indicated for the prevention and treatment of malignant hyperthermia (MH). MH is a rare but potentially deadly hypermetabolic crisis that typically occurs as a complication of general anesthesia. In MH, evidence points to an intrinsic abnormality of skeletal muscle tissue. In affected humans, it has been postulated that "triggering agents" (e.g., general anesthetics and depolarizing neuromuscular blocking agents) produce a change within the cell which results in an elevated myoplasmic calcium. This activates acute cellular processes that cascade to the MH crisis. RYANODEX addresses the MH-related intracellular calcium dyregulation to treat the life-threatening hypermetabolic and hyperthermic crisis. It functions by preventing, attenuating, or reversing the hyperthermic and hypermetabolic cascade associated with MH. Dantrolene sodium reverses the calcium release from the sarcoplasmic reticulum leading to skeletal muscle relaxation and subsequent recovery from the hypermetabolic state.

For the treatment of MH, RYANODEX is administered by intravenous push at a maximum dose of 1 mg/kg. If the physiologic and metabolic abnormalities of MH continue, RYANODEX is administered up to the maximum cumulative dosage of 10 mg/kg. If physiologic and metabolic abnormalities reappear, RYANODEX dosing is repeated by IV push starting with 1 mg/kg. For the prevention of MH, RYANODEX 2.5 mg/kg is administered over a period of at least 1 minute, starting approximately 7.5 minutes prior to surgery. Additional administrations may occur. RYANODEX is supplied as a lyophilized mixture in a 20 mL vial containing 250 mg of dantrolene sodium for reconstitution with 5 mL sterile water for injection.

The applicant comments that a new code is warranted because no other current HCPCS code describes this single-source drug.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establisha codeto identifyRYANODEX has not been approved. RYANODEX is used exclusively in the inpatient hospital setting, and as such, it is not suitable for coding in HCPCS Level II.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker respectfully disagrees with CMS' preliminary recommendation for a J code for RYANODEX which is indicated for the treatment of malignant hyperthermia in conjunction with appropriate supportive measures and for the prevention of MH in patients at high risk.

FINAL DECISION

This request to establish a code to identify RYANODEX has not been approved, because RYANODEX is not suitable for coding in HCPCS Level II due to settings of use. CMS recommends the applicant consider pursuing a pass-through code for Hospital Outpatient use, as claimed.

Tuesday, May 15, 2018

Agenda Item # 28

Application# 18.031

TOPIC

Request to establish a new Level II HCPCS code to identify copanlisib for injection, for intravenous use, Trade Name: ALIQOPA.

Applicant's suggested language: Jxxxx-"copanlisib (ALIQOPA), 1 mg".

BACKGROUND

Bayer Pharmaceutical, Inc. submitted a request to establish a new Level II HCPCS code to identify ALIQOPA. ALIQOPA is a kinase inhibitor indicated for the treatment of patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies. According to the applicant, copanlisib is a new molecular entity and is an inhibitor of phosphatidylinositol-3-kinase (PI3K) with inhibitory activity predominantly against PI3K-α and P13Kσ isoforms expressed in malignant B cells. Copansilib has been shown to induce tumor cell death by apoptosis and inhibition of proliferation of primary malignant B cell lines.

The recommended dosage for copanlisib is 60 mg administered intravenously, as a one hour infusion, on days 1, 8, and 15 of a 28-day treatment cycle on an intermittent schedule (3 weeks on and 1 week off). Each 60 mg single-dose vial of copanlisib is supplied as a lyophilized solid for reconstitution. Reconstituted concentration is 15 mg/mL.

The applicant comments that a new code is warranted in order to "help ensure patients are billed correctly by their insurance plans for cost sharing"; and to "ensure appropriate identification and payment of Medicaid rebates."

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX "Injection, copanlisib, 1 mg." Effective 1/1/19.

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 recommendation.

FINAL DECISION

Establish J9057 "Injection, copanlisib, 1 mg." Effective 1/1/19.