

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

Wednesday, May 15, 2019

This HCPCS Code Application Summary document includes a summary of each HCPCS code application discussed at the May 15, 2019 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' 2019-2020 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: <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html>

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 1

Application # 19.024

TOPIC

Request to establish a new Level II HCPCS code to identify NUZYRA (omadacycline) for injection.

Applicant's suggested language: JXXXX "Injection, omadacycline, 100 mg".

BACKGROUND

Paratek Pharmaceuticals, Inc. submitted a request to establish a new Level II HCPCS code to identify NUZYRA (omadacycline) for injection.

Nuzyra is a tetracycline class antibacterial indicated for the treatment of Community-Acquired Bacterial Pneumonia (CABP), Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in adults caused by susceptible microorganisms. For the treatment of adults with Community Acquired Bacteria Pneumonia, the dosage is 200 mg intravenous infusion over 60 minutes on the first day, and 100 mg intravenous infusion once daily infused over 30 minutes for 7 to 14 Days. For the treatment of adults with Acute Bacterial Skin Structure and Skin infection (ABSSSI), the recommended dosage of NUZYRA is 200 mg intravenous infusion over 60 minutes on the first day, and 100 mg intravenous infusion once daily infused over 30 minutes for 7 to 14 Days.

Nuzyra is supplied as 100 mg of omadacycline (equivalent to 131 mg omadacycline tosylate) as a lyophilized powder in a single dose vial for reconstitution and further dilution before intravenous infusion.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code JXXXX "Injection, omadacycline, 1 mg".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary recommendation.

FINAL DECISION

CMS established new Level II HCPCS code J0121 "Injection, omadacycline, 1 mg". Effective 10/01/2019.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 2

Application # 19.054

TOPIC

Request to establish a new Level II HCPCS code to identify plazomicin. Trade Name: Zemdri.

Applicant's suggested language: JXXXX- Injection, plazomicin, 5 mg.

BACKGROUND

Achaogen, Inc. submitted a request to establish a new Level II HCPCS code to identify Zemdri, an injection for an intravenous use.

According to the applicant, Zemdri is an aminoglycoside antibacterial drug that contains plazomicin. It is indicated for the treatment of patients 18 years of age or older with cUTI, including pyelonephritis.

The recommended dosage regimen of Zemdri is 15 mg/kg administered every 24 hours by IV infusion over 30 minutes in patients 18 years of age or older and with CL_{cr} greater than or equal to 60 ml/min. Recommended duration of treatment is 4 to 7 days for cUTI.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code J02XX "Injection, Plazomicin, 5 mg".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION

CMS established new Level II HCPCS code J0291 "Injection, Plazomicin, 5 mg". Effective 10/01/2019.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 3

Application # 19.097

TOPIC

Request to establish a new Level II HCPCS code to identify Eravacycline, Trade Name: XERAVA.

Applicant's suggested language: "Xerava for injection, 50 mg per vial".

BACKGROUND

Tetraphase Pharmaceuticals, Inc., submitted a request to establish a new Level II HCPCS code to identify XERAVA. XERAVA is a tetracycline class antibacterial indicated for the treatment of complicated intra-abdominal infections in patients 18 years of age and older. The recommended dose regimen of XERAVA is 1 mg/kg every 12 hours. Administer intravenous infusions of XERAVA over approximately 60 minutes every 12 hours. The recommended duration of treatment with XERAVA for 4 to 14 days.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code JXXXX "Injection, eravacycline, 1 mg"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary recommendation. The speaker requested that CMS finalize its preliminary recommendation for XERAVA, the first fully synthetic tetracycline.

FINAL DECISION

CMS established new Level II HCPCS code J0122 "Injection, eravacycline, 1 mg." Effective 10/01/2019.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 4

Application # 19.048

TOPIC

Request to establish a new Level II HCPCS code to identify iclaprim mesylate, Trade Name: Xultenba.

BACKGROUND

Motif BioSciences, Inc., submitted a request to establish a new Level II HCPCS code to identify Xultenba for intravenous use. According to applicant, Xultenba is an antimicrobial agent, indicated for the treatment of ABSSI cellulitis/erysipelas, abscess, wound infection, or surgical site infection) caused by Gram-positive bacteria. It is supplied as a sterile-solution that must be further diluted prior to intravenous infusion.

PRELIMINARY HCPCS CODING RECOMMENDATION

Xultenba is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. We refer the applicant to CMS' pass-through program for consideration of coding for reporting use in HOPPS and ASC settings. For hospital inpatient use, the product is included in the bundled payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

We received no comments at CMS' HCPCS Public Meeting regarding this application.

FINAL DECISION

Xultenba is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. We refer the applicant to CMS' pass-through program for consideration of coding for reporting use in HOPPS and ASC settings. For hospital inpatient use the product is included in the bundled payment.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 5

Application # 19.065

TOPIC

Request to establish a new Level II HCPCS codes to identify aripiprazole lauroxil. Trade Name: Aristada Initio.

Applicants suggested language: JXXXX, injection, aripiprazole lauroxil single starting dose, 1 mg.

BACKGROUND

Alkermes Inc. submitted a request to establish a new Level II HCPCS code to identify Aristada Initio (Aripiprazole Lauroxil), an intramuscular injection.

According to the applicant, Aristada Initio, in combination with a single dose of Aripiprazole, is indicated for the initiation of Aristada when used for the treatment of schizophrenia in adults. Aristada Initio 675 mg is only to be used as a single dose to initiate Aristada treatment or to re-initiate Aristada treatment following a missed dose of Aristada. Aristada Initio is only to be administered as an intramuscular injection. To initiate treatment with Aristada Initio, administer 1 injection of Aristada Initio 675 mg and oral Aripiprazole 30 mg in conjunction with the first Aristada injection (441 mg, 662 mg, 882 mg, or 1064 mg). The first Aristada injection may be administered on the same day as Aristada Initio or up to 10 days thereafter.

PRELIMINARY HCPCS CODING RECOMMENDATION

- 1) Establish new Level II HCPCS code JXXXX "Injection, aripiprazole lauroxil, (Aristada Initio), 1 mg"
- 2) Revise existing code J1942, which currently reads: "Injection, aripiprazole lauroxil, 1 mg"; to instead read: "Injection, aripiprazole lauroxil, (Aristada), 1 mg"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary recommendation.

FINAL DECISION

- 1) Establish new Level II HCPCS code J1943 "Injection, aripiprazole lauroxil, (Aristada Initio), 1 mg" Effective 10/1/19

2) Discontinue existing code J1942 which currently reads: "Injection, aripiprazole lauroxil, 1 mg
Effective 10/1/19

3) Establish new level II HCPCS code J1944 "Injection, aripiprazole lauroxil, (Aristada), 1 mg"
Effective 10/1/19.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 6

Application # 19.023

TOPIC

Request to establish a new Level II HCPCS code to identify risperidone extended-release injectable suspension. Trade name: Perseris.

Applicant's suggested language: Injection, risperidone (PERSERIS), per 1 mg.

BACKGROUND

Indivior Inc. submitted a request to establish a new Level II HCPCS code to identify Perseris (risperidone) extended-release injectable suspension for abdominal subcutaneous use only.

PERSERIS is an atypical antipsychotic indicated for use in the treatment of schizophrenia in adults.

PRELIMINARY HCPCS CODING RECOMMENDATION

1. Establish new Level II HCPCS code JXXXX "Injection, risperidone, (perseris), 0.5 mg
2. Revise existing code J2794, which currently reads: "Injection, risperidone, long acting, 0.5 mg"; to instead read: "Injection, risperidone (risperdal consta), 0.5 mg".

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION

1. CMS established new Level II HCPCS code J2798 "Injection, risperidone, (perseris), 0.5 mg". Effective 10/01/2019
2. CMS revised existing code J2794 which currently reads: "Injection, risperidone, long acting, 0.5 mg"; to instead read: "Injection, risperidone (risperdal consta), 0.5 mg". Effective 10/01/2019.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 7

Application # 19.094

TOPIC

Request to establish a new HCPCS level II code to identify Zulresso (brexanolone) injection 5 mg/ml.

BACKGROUND

Sage Therapeutics, Inc. submitted a request to establish a new HCPCS level II code to identify Zulresso (brexanolone) injection 5 mg/ml.

Indication for use of Zulresso (brexanolone) injection 5 mg/ml is postpartum depression.

The recommended maximum dose for ZULRESSO is 90 mcgs/kg/h administered as a continuous intravenous solution over 60 hours (2.5 days) as follows:

0 to 4 hours: Initiate with a dosage of 30 mcgs/kg/hour

4 to 24 hours: Increase dosage to 60 mcg/kg/hour

24 to 52 hours: Increase dosage to 90 mcgs/kg/hour (a reduction in dosage to 60 mcg/kg/hour may be considered during this time period for patients who do not tolerate 90mcg/kg/hour).

52 to 56 hours: Decrease dosage to 60 mcg/kg/hour

56 to 60 hours: Decrease dosage to 30 mcg/kg/hour

PRELIMINARY HCPCS CODING RECOMMENDATION

Zulresso is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. We refer the applicant to CMS' pass-through program for consideration of coding for reporting use in HOPPS settings. For hospital inpatient use the product is included in the bundled payment.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation, commenting that new data supports use of Zulresso in other than hospital in-patient and hospital out-patient settings.

FINAL DECISION

Zulresso is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. For hospital inpatient use the product is included in the bundled payment. Newly established pass-through code C9055 "Injection, brexanolone, 1mg" is available for assignment by insurers, if they deem appropriate to identify hospital outpatient use.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 8

Application # 19.064

TOPIC

Request to establish a new Level II HCPCS code to identify an injectable sodium hyaluronate.
Trade Name: Triluron.

Applicant's suggested language: JXXXX, Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg.

BACKGROUND

On behalf of Fidia Pharma USA Inc., a request was submitted to establish a new Level II HCPCS code to identify Triluron™ (Sodium Hyaluronate), a sterile solution for intra-articular injection.

According to the applicant, Triluron™ is indicated for the treatment of pain in osteoarthritis of knee in patients who have failed to respond adequately to conservative non-pharmacological therapy or to simple analgesics.

Triluron™ is intended to be injected into the knee joint by intra-articular injection. A treatment cycle consists of three injections with each injection consisting of 2 ml of Triluron™, given at weekly intervals.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code J7XXX "Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary recommendation.

FINAL DECISION

CMS established new Level II HCPCS code J7332 "Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg". Effective 10/01/2019.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 9

Application # 19.053

TOPIC

Request to establish a new Level II HCPCS code to identify Phenylephrine and Ketorolac ophthalmic solution. Trade Name: Omidria.

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

BACKGROUND

Omeros Corporation submitted a request to establish a new Level II HCPCS code to identify Omidria. According to the applicant, Omidria is added to ophthalmic irrigation solution used during cataract surgery or IOL replacement procedures and is indicated for maintaining pupil size by preventing intraoperative miosis (pupil constriction) and for reducing postoperative pain.

Omidria must be diluted prior to intraocular use. For administration to patients undergoing cataract surgery or IOL replacement, 4 ml of Omidria is diluted in 500 ml of ophthalmic irrigation solution and administered intracamerally (into the patient's eye) by the physician.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code JXXXX "Phenylephrine 10.6 mg/ml and Ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary recommendation. The speaker asked to correct a typographical error in the preliminary recommendation by changing phenylephrine dose from 10.6 to 10.16 mg/mL per FDA labeling. The speaker also reiterated the original recommendation to use 4 mL as the dose descriptor, because it is the only available size.

FINAL DECISION

CMS established new Level II HCPCS code J1097 "Phenylephrine 10.16 mg/ml and Ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml" Effective 10/01/2019.

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Agenda Item # 10

Application # 19.049

TOPIC

Request to establish a new Level II HCPCS code to identify a 3 mm cylindrical ophthalmic drug insert. Trade Name: Dextenza.

Applicant's suggested language: JXXXX, Dextenza, Ophthalmic insert, lacrimal, dexamethasone, 0.4 mg.

BACKGROUND

Ocular Therapeutix submitted a request to establish a new Level II HCPCS code to identify Dextenza®, a 3 mm cylindrical ophthalmic drug insert. Dextenza® is indicated for the treatment of ocular pain following ophthalmic surgery.

Dextenza® is a resorbable ophthalmic drug insert that is inserted non-surgically in the lower lacrimal punctum and into the canaliculus. A single Dextenza® releases a 0.4 mg dose of dexamethasone for up to 30 days following insertion.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code JXXXX "Dexamethasone, lacrimal ophthalmic insert, 0.1 mg"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION

CMS established new Level II HCPCS code J1096 "Dexamethasone, lacrimal ophthalmic insert, 0.1 mg" Effective 10/01/2019.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 11

Application # 19.028

TOPIC

Request to establish one new Level II HCPCS code to identify Yutiq, and to revise existing code J7313 (Iluvien).

Applicant's suggested language for a new code: JXXXX Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg.

Applicant's suggested language for revised code: J7313 Injection, fluocinolone acetonide, intravitreal implant (Iluvien), 0.01 mg.

BACKGROUND

EyePoint Pharmaceuticals, Inc. submitted to request to establish a new code to identify Yutiq (fluocinolone acetonide intravitreal implant), 0.18 mg for treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

Yutiq is non-bio erodible intravitreal implant drug delivery system containing 0.18 mg fluocinolone acetonide, designed to release fluocinolone acetonide at an initial rate of 0.25 mcg/day, and lasting 36 months. The intravitreal injection procedure should be carried out under aseptic conditions. Following the intravitreal injection, patients should be monitored for elevation in intraocular pressure and for endophthalmitis.

PRELIMINARY HCPCS CODING RECOMMENDATION

- 1) Establish new Level II HCPCS code JXXXX "Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg"
- 2) Revise existing code J7311, which currently reads: "Fluocinolone acetonide, intravitreal implant"; to instead read: "Injection, Fluocinolone acetonide, intravitreal implant (retisert), 0.01 mg"
- 3) Revise existing code J7313 which currently reads: "Injection, fluocinolone acetonide, intravitreal implant, 0.01 mg"; to instead read: "Injection, fluocinolone acetonide, intravitreal implant (Iluvien), 0.01 mg"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION

- 1) CMS established new Level II HCPCS code J7314 "Injection, fluocinolone acetonide, intravitreal implant (Yutiq), 0.01 mg" Effective 10/01/2019
- 2) Revised existing code J7311 which currently reads: "Fluocinolone acetonide, intravitreal implant"; to instead read: "Injection, Fluocinolone acetonide, intravitreal implant (retisert), 0.01 mg".
- 3) Revised existing code J7313 which currently reads: "Injection, fluocinolone acetonide, intravitreal implant, 0.01 mg"; to instead read: "Injection, fluocinolone acetonide, intravitreal implant (iluvien), 0.01 mg"

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 12

Application # 19.032

TOPIC

Request to establish a new Level II HCPCS code to identify Prograf Granules (tacrolimus for oral suspension). Trade name: Prograf Granules.

Applicant's suggested language: JXXXX tacrolimus, granules, per 0.2 mg.

BACKGROUND

Astellas Pharma US, Inc. submitted a request to establish a new code to identify Prograf Granules (tacrolimus for oral suspension), an orally administered drug. According to the applicant, Prograf Granules oral suspension is indicated for prophylaxis of organ rejection in pediatric patients receiving allogenic liver, kidney or heart transplant.

Prograf Granules are dissolved in water and administered orally as a liquid suspension. The initial oral dosage for pediatric patients with kidney, liver, or heart transplants, along with the blood concentration monitoring is patient specific.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code J7507 "Tacrolimus, immediate release, oral, 1 mg", adequately describes Prograf Granules and is available for assignment by insurers. The NDA approval, by itself, does not establish Prograf Granules as a sole source product. There are multiple oral forms of Tacrolimus that are AP rated in the FDA orange book. And in that case, Prograf Granules can be included in the same code. Separate pricing in accordance with section 1847A of the Social Security Act does not apply to this multisource drug. CMS has consulted its ESRD staff and a specific code for ESRD use is not necessary because, if used, the immunosuppressant would not be considered a renal dialysis service.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

We received no comments at CMS' HCPCS Public Meeting regarding this application, or in response to our published preliminary recommendation.

FINAL DECISION

Existing code J7507 "Tacrolimus, immediate release, oral, 1 mg", adequately describes Prograf Granules and is available for assignment by insurers. The NDA approval, by itself, does not establish Prograf Granules as a sole source product. There are multiple oral forms of Tacrolimus that are AP rated in the FDA orange book. And in that case, Prograf Granules can be included in

the same code. Separate pricing in accordance with section 1847A of the Social Security Act does not apply to this multisource drug. CMS has consulted its ESRD staff and a specific code for ESRD use is not necessary because, if used, the immunosuppressant would not be considered a renal dialysis service.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 13

Application # 19.062

TOPIC

Request to establish a new Level II HCPCS code to identify Ravulizumab-cwvz, an injectable drug proposed for treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). Trade Name: Ultomiris™.

Applicant's suggested language: JXXXX- injection, ravulizumab-cwvz, up to 10 mg.

BACKGROUND

Alexion Pharmaceuticals, Inc. submitted a request to establish a new Level II HCPCS code to identify Ultomiris™ (ravulizumab-cwvz). According to the applicant, Ultomiris™ was approved by the FDA for treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). Ultomiris™ is administered via IV infusion once every 8 weeks starting 2 weeks after the initial loading dose. Actual dosing is based on body weight. It is supplied for injection via IV infusion 300 mg/30 ml (10 mg/ml) in a single-dose vial.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code JXXXX "Injection, ravulizumab-cwvz, 10 mg"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION

CMS established new Level II HCPCS code J1303 "Injection, ravulizumab-cwvz, 10 mg". Effective 10/01/2019.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 14

Application # 19.056

TOPIC

Request to establish a new Level II HCPCS code to identify patisiran. Trade Name: Onpattro (patisiran).

Applicant's suggested language: JXXXX- Injection, patisiran, 0.1 mg.

BACKGROUND

Alnylam Pharmaceuticals, Inc. submitted a request to establish a new Level II HCPCS code to identify Onpattro, a lipid complex injection for an intravenous use.

According to the applicant, Onpattro is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

The recommended dose of Onpattro is 0.3 mg/kg administered via IV infusion once every 3 weeks.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code JXXXX "Injection, Patisiran, 0.1 mg"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION

CMS established new Level II HCPCS code J0222 "Injection, Patisiran, 0.1 mg" Effective 10/01/2019.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 15

Application # 19.042

TOPIC

Request to establish a new Level II HCPCS code to identify sufentanil sublingual tablet, Trade Name: Dsuvia™.

Applicant's suggested language: JXXXX "sufentanil (DSUVIA), sublingual (for healthcare provider administration), 30 mcg.

BACKGROUND

AcelRx Pharmaceuticals, Inc., submitted a request to establish a new Level II HCPCS code for Dsuvia.

Dsuvia contains sufentanil, an opioid agonist, and is indicated for use in adults in REMS certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain, severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

PRELIMINARY HCPCS CODING RECOMMENDATION

Dsuvia is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. We refer the applicant to CMS' pass-through program for consideration of coding for reporting use in HOPPS and ASC settings.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation to not establish J code and appreciates referral to HOPPS for pass thru code.

FINAL DECISION

Dsuvia is not suitable for coding in Level II HCPCS due to setting of use.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 16

Application # 19.040

TOPIC

Request to establish a new Level II HCPCS code to identify Takhzyro™ (lanadelumab-flyo), indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older. Brand name: Takhzyro.

Applicant's suggested language: Jxxxx- injection, lanadelumab-flyo, per 10 mg.

BACKGROUND

Shire Pharmaceuticals submitted a request to establish a new code to identify Takhzyro™ (lanadelumab-flyo), an injection for subcutaneous administration.

According to the applicant, Takhzyro™ is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older.

The recommended starting dose is 300 mg every 2 weeks. A dosing interval of 300 mg every 4 weeks is also Effective and may be considered if the patient is well controlled for more than 6 months.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code JXXXX "Injection, lanadelumab-flyo, 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)"

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary recommendation.

FINAL DECISION

CMS established new Level II HCPCS code J0593 "Injection, lanadelumab-flyo, 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)" Effective 10/01/2019.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 17

Application # 19.083

TOPIC

Request to establish to a new Level II HCPCS code to identify Glucagon, Trade Name: Glucagon for injection (Fresenius Kabi).

Applicant's suggested language: "Injection, Glucagon (Fresenius Kabi), 1 mg"

BACKGROUND

Fresenius Kabi USA, LLC, submitted a request to establish a new Level II HCPCS code to identify glucagon for injection. According to the applicant, Glucagon for injection is indicated to treat severe hypoglycemic reactions, which may occur in patients with diabetes mellitus treated with Insulin; and for use as a diagnostic aid during radiologic examinations to temporarily inhibit movement of the gastroenterologist tract. Reconstitute lyophilized powder with sterile water for injection before use. Determine dose based on diagnostic procedure, route of administration and procedure duration. To inhibit stomach and small bowel motility the dose is 0.2 to 0.5 mg given intravenously or 1 mg given intramuscularly. To inhibit colon motility the dose is 0.5 to 0.75 mg given intravenously or 1 to 2 mg given intramuscularly.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing Multi-source code J1610 "Injection, Glucagon Hydrochloride, per 1 mg" adequately describes the product that is the subject of this application. As Glucagon was coded and marketed prior to October 1, 2003, it is grandfathered and not subject to the separate pricing requirements under section 1847A of the Social Security Act. The NDA approval, by itself, does not establish Glucagon as a sole source product.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

We received no comments at CMS' HCPCS Public Meeting regarding this application, or in response to our published preliminary recommendation.

FINAL DECISION

Existing Multi-source code J1610 "Injection, Glucagon Hydrochloride, per 1 mg" adequately describes the product that is the subject of this application. As Glucagon was coded and marketed prior to October 1, 2003, it is grandfathered and not subject to the separate pricing requirements under section 1847A of the Social Security Act. The NDA approval, by itself, does not establish Glucagon as a sole source product.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 18

Application # 19.081

TOPIC

Request to revise existing Level II HCPCS code J1443, which currently reads: "Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron", to instead read: "Ferric pyrophosphate citrate solution ampule, 0.1 mg of iron in hemodialysate".

BACKGROUND

Rockwell Medical submitted a request to revise the descriptor of existing code J1443 which currently reads: "Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron" to instead read: "Ferric pyrophosphate citrate solution ampule, 0.1 mg of iron in hemodialysate", to adequately describe the Triferic solution ampule, administered through hemodialysate.

Triferic solution ampule is added to liquid bicarbonate concentrate, prior to use in the dialysis machine, for generation of hemodialysate, and is indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD). Add one 5 ml Triferic ampule to 2.5 gallons of bicarbonate concentrate to achieve a final concentration of Triferic® iron (III) in the final hemodialysate is 2µM (110 mcg/L). Add 50 ml ampule of Triferic to each 25 gallons of bicarbonate concentrate to achieve a final concentration of Triferic iron (III) in the final hemodialysate is 2µM (110 mcg/L).

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to revise existing code J1443 is not approved, because the requested revision does not improve the code. The existing code J1443 "Injection, ferric pyrophosphate citrate solution, 0.1 mg of iron" adequately describes Triferic liquid and is available for assignment by insurers, if they deem appropriate. Use of the JE modifier "administered via dialysate" together with code J1443, addresses the applicant's request to specify use of this product in hemodialysate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary recommendation because Triferic can only be administered by dialysate. The speaker stated a preference for a specific code as requested but acknowledged that existing code J1443 plus JE modifier adequately describes Triferic ampule, particularly CMS proposed a separate code for powder.

FINAL DECISION

This request to revise existing code J1443 is not approved, because the requested revision does not improve the code. The existing code J1443 "Injection, ferric pyrophosphate citrate solution,

0.1 mg of iron" adequately describes Triferic liquid and is available for assignment by insurers, if they deem appropriate.

Use of the JE modifier "administered via dialysate" together with code J1443, addresses the applicant's request to specify use of this product in hemodialysate.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 18

Application # 19.082

TOPIC

Request to establish a new Level II HCPCS code to identify Ferric pyrophosphate citrate powder, Trade Name: Triferic powder packet.

Applicant's suggested language: JXXXX "Ferric pyrophosphate citrate powder, 0.1 mg of iron in hemodialysate".

BACKGROUND

Rockwell Medical submitted a request to establish a new Level II HCPCS code to identify Triferic powder packet. Triferic is an iron replacement product indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD). It is supplied as 272 mg of iron (III) per packet as Triferic powder. Add one packet of Triferic powder to 25 gallons of bicarbonate concentrate to achieve a final concentration of Triferic iron (III) in the final hemodialysate is 2 μ M (110 mcg/L).

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish new Level II HCPCS code J1444 "Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron", Effective 7/1/19. This code would be used with the existing "JE" modifier "Administered via dialysate", when administered via dialysate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' preliminary recommendation.

FINAL DECISION

CMS established new Level II HCPCS code J1444 "Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron", effective 7/1/19. This code would be used with the existing "JE" modifier, Administered via dialysate", when administered via dialysate.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 19

Application # 19.092

TOPIC

Request to establish another Level II HCPCS code to identify Iohexol, Trade Name: Omnipaque.

Applicant suggested language: Q99XX "Low osmolar contrast material, 1-99 mg/ml iodine concentration, per ml".

BACKGROUND

General Electric Health Care, submitted a request to establish another Level II HCPCS code to identify Omnipaque. Omnipaque injection is a radiographic contrast agent indicated for intrathecal, intravascular, oral, rectal, intraarticular and body cavity use. Omnipaque oral solution is indicated for oral use only in conjunction with omnipaque injection administered intravenously for computed tomography (CT) of the abdomen. The concentration and volume required will depend on the indication, size, and condition of the patient, and the equipment, and imaging technique used.

PRELIMINARY HCPCS CODING RECOMMENDATION

Contrast material is included in the CPT procedure code for CT with contrast. And as such, additional coding will be redundant.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker requested CMS reconsideration of its preliminary decision to not issue a new code to the series of existing codes for low osmolar material and to issue a code to reflect the nomenclature: Low osmolar contrast material, 1-99mg/ml iodine CONCENTRATION, per ml.

FINAL DECISION

CMS was unable to find policy on the part of any insurance sector that would indicate a need for a code to identify Low osmolar contrast material, 1-99 mg/ml iodine concentration.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 20

Application # 19.075

TOPIC

Request to establish a new Level II HCPCS code to identify a corticosteroid-eluting implant indicated for the treatment of nasal polyps in patients 18 years of age who have had ethmoid sinus surgery. Trade Name: Sinuva (mometasone furoate) Sinus Implant.

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

BACKGROUND

Intersect ENT submitted a request to establish a new Level II HCPCS code to identify Sinuva, a mometasone furoate implant that is injected into the sinus by a physician. According to the applicant, Sinuva is a corticosteroid-eluting implant indicated for the treatment of nasal polyps in patients 18 years of age who have had ethmoid sinus surgery. The dosage of Sinuva is 1,350 mcg of mometasone furoate. Sinuva is placed intrasinally among the sinus polyps and gradually releases corticosteroid over 90 days.

PRELIMINARY HCPCS CODING RECOMMENDATION

- 1) Establish new Level II HCPCS code J7XXX "Mometasone furoate, implant, 10 micrograms"
- 2) Discontinue existing code S1090, which currently reads: "Mometasone furoate sinus implant, 370 micrograms", because it is duplicative of JXXXX.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agreed with CMS' recommendation to establish a new code and specifically requested that CMS add the word "sinus" to the descriptor.

FINAL DECISION

- 1) CMS established new Level II HCPCS code J7401 "Mometasone furoate sinus implant, 10 micrograms". Dose descriptor of 10 micrograms is consistent with CMS' longstanding convention of using the lowest common denominator. This code can be reported in multiples in the units column on the claim form.
- 2) Discontinued existing code S1090, which currently reads: "Mometasone furoate sinus implant, 370 micrograms", because it is duplicative of J7401, effective 10/1/19.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 21

Application # 19.080

TOPIC

Request to establish a new Level II HCPCS code to identify coagulation factor Xa (recombinant), inactivated-zhzo. Trade Name: Andexxa.

Applicant's suggested language: JXXXX, Injection, coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa), 100 mg.

BACKGROUND

Portola Pharmaceuticals submitted a request to establish a new Level II HCPCS code to identify Andexxa. According to the applicant, Andexxa, coagulation factor Xa (recombinant), inactivated-zhzo is a recombinant modified human Factor Xa (FXa) protein indicated for patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. This indication is approved under accelerated approval based on the change from baseline in anti-FXA activity in healthy volunteers. An improvement in hemostasis has not been established. Continue approval for this indication may be contingent upon the results of studies to demonstrate an improvement in hemostasis patients. Andexxa has not been shown to be Effective for, and is not indicated for, the treatment of bleeding related to any FXa inhibitors other than apixaban or rivaroxaban.

Andexxa dosage is based on the specific FXa inhibitor, dose of FXa inhibitor, and time since the patient's last dose of FXa inhibitor. Administered as an intravenous bolus, with a target rate of 30 mg/min, followed by continuous infusion for up to 120 minutes.

PRELIMINARY HCPCS CODING RECOMMENDATION

Andexxa is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. Existing pass-through code C9041 "Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10 mg" is available for assignment by insurers, if they deem appropriate to identify hospital outpatient use.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker indicated the "C code is not consistently recognized by payers, but a J code would function better".

FINAL DECISION

Andexxa is not suitable for coding in Level II HCPCS outside of CMS' pass-through coding process due to setting of use. Existing pass-through code C9041 "Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10 mg" is available for assignment by insurers, if they deem appropriate to identify hospital outpatient use.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 22

Application # 19.078

TOPIC

Request to establish a new Level II HCPCS code to identify a human rabies immunoglobulin (HRIG) biological indicated for passive, transient post-exposure prophylaxis (PEP) of rabies infection, when given immediately after contact with a rabid or possibly rabid animal. Trade Name: Kedrab, Rabies Immune Globulin (Human).

Applicant's suggested language: "JXXXX Injection, rabies immune globulin, human, solvent/detergent and heat-treated (Kedrab), 150 i.u."

BACKGROUND

Kedrion Biopharma Inc. submitted a request to establish a new Level II HCPCS code to identify Kedrab, a human rabies immunoglobulin (HRIG).

According to the applicant, Kedrab is a human rabies immunoglobulin (HRIG) biological indicated for passive, transient post-exposure prophylaxis (PEP) of rabies infection, when given immediately after contact with a rabid or possibly rabid animal. Kedrab should be administered concurrently with a full course of rabies vaccine. Kedrab is used for wound infiltration and intramuscular injection.

The recommended dose of Kedrab is 20 IU/kg weight, given at the time of the first vaccine dose.

PRELIMINARY HCPCS CODING RECOMMENDATION

The CMS has carefully considered this request to establish a unique Level II HCPCS code to identify Kedrab, together with input from the drug pricing component of CMS' Hospital and Ambulatory payment group and from the American Medical Association, in follow-up to specific concerns noted by Kedrion within this application. In its final coding decision to a prior (2018-2019) request from Kedrion to establish distinct Level II HCPCS codes for Rabies Immune globulin products, the CMS discussed that the taxonomy for Rabies Immune globulin products resides in the HCPCS Level I Current Procedural Terminology (CPT) code set, maintained by the American Medical Association (AMA). And we referred Kedrion to the AMA to resolve the CPT coding concerns expressed in its 2018-2019 application to CMS for a Level II HCPCS code. It is our understanding that Kedrion did not submit an application to the AMA for a unique code to identify Kedrab, and this specific request was only made to CMS. As the AMA maintains the series of Rabies immune globulin codes, CMS suggests that Kedrion provide the AMA with the opportunity to consider its request to uniquely code Kedrab within its series of Rabies immune globulin codes. In the meantime, CMS has a mechanism to establish a separate price for Kedrab in accordance with section 1847A of the Social Security Act.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

No comments were offered at CMS' HCPCS Public Meeting regarding this application or in response to our published preliminary recommendation.

FINAL DECISION

The CMS has carefully considered this request to establish a unique Level II HCPCS code to identify Kedrab, together with input from the drug pricing component of CMS' Hospital and Ambulatory payment group and from the American Medical Association, in follow-up to specific concerns noted by Kedrion within this application. In its final coding decision to a prior (2018-2019) request from Kedrion to establish distinct Level II HCPCS codes for Rabies Immune globulin products, the CMS discussed that the taxonomy for Rabies Immune globulin products resides in the HCPCS Level I Current Procedural Terminology (CPT) code set, maintained by the American Medical Association (AMA). And we referred Kedrion to the AMA to resolve the CPT coding concerns expressed in its 2018-2019 application to CMS for a Level II HCPCS code. It is our understanding that Kedrion did not submit an application to the AMA for a unique code to identify Kedrab, and this specific request was only made to CMS. As the AMA maintains the series of Rabies immune globulin codes, CMS suggests that Kedrion provide the AMA with the opportunity to consider its request to uniquely code Kedrab within its series of Rabies immune globulin codes. In the meantime, CMS has a mechanism to establish a separate price for Kedrab in accordance with section 1847A of the Social Security Act.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 23

Application # 19.098

TOPIC

Request to establish a series of six new Level II HCPCS codes to identify High potency polymerized cross-linked sucralfate (HPPCLS), Trade Name: ProThelial.

Applicant's suggested language:

“JXXXX Mucositis Paste, 75ml-Polymerized Cross-linked Sucralfate, ProThelial 10%”,

“JXXXX Mucositis Paste, 120ml-Polymerized Cross-linked Sucralfate, ProThelial 10%”,

“JXXXX Mucositis Paste, 125ml-Polymerized Cross-linked Sucralfate, ProThelial 10%”,

“JXXXX Mucositis Paste, 250ml-Polymerized Cross-linked Sucralfate, ProThelial 10%”,

“JXXXX Mucositis Paste, 500ml-Polymerized Cross-linked Sucralfate, ProThelial 10%, 125ml x 4 units”,

“JXXXX Mucositis Paste, 500ml-Polymerized Cross-linked Sucralfate, ProThelial 10%, 250ml x 2 units”.

BACKGROUND

Mueller Medical International LLC, submitted a request to establish a series of 6 new Level II HCPCS code to identify ProThelial products. According to applicant, ProThelial forms a protective layer over the oral mucosa by adhering to the mucosal surface which allows it to protect against further irritation and relieve pain. The paste may be used in the management of mouth lesions of all types including aphthous ulcer, stomatitis, mucositis, minor lesions, chafing and traumatic ulcers, abrasions caused by braces and ill fitting dentures, and lesions associated with oral surgery.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing NDC codes are available for assignment by all insurers to identify these ProThelial products, if they deem appropriate. As such, adding Level II HCPCS codes would be redundant and unnecessary. Level II HCPCS codes for the purpose of reporting to Medicare on claims in lieu of NDC codes is unnecessary because these orally administered products are not reportable under Part B, and they are also not reportable under Part D, because they are not FDA approved as drugs.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker requested that CMS reconsider its recommendation. The speaker stated there has been a national program operating need for a code to report an effective antidote for chemotherapy radiation mucositis (CRTM).

FINAL DECISION

CMS was unable to find policy on the part of any insurance sector that would indicate a need for a code to identify mucositis paste, polymerized cross linked sucralfate.

CMS HCPCS Public Meeting May 15, 2019

Agenda Item # 24

Application # 19.026

TOPIC

Request to revise existing Level II HCPCS code J3380, which currently reads “Injection, vedolizumab, 1 mg” to instead read “for intravenous injection, vedolizumab, 1 mg”.

BACKGROUND

Takeda Pharmaceuticals U.S.A., Inc., submitted a request to revise existing Level II HCPCS code J3380 for Entyvio (Vedolizumab) to specify intravenous injection, in order to distinguish this code from a potential future clearance for subcutaneous injection.

Entyvio (Vedolizumab) is an integrin receptor antagonist indicated for the treatment of adult patients with moderate to severe ulcerative colitis or Crohn's disease.

Recommended dosage in ulcerative colitis and Crohn's disease: 300 mg infused intravenously over approximately 30 minutes at zero, two and six weeks, then every eight weeks thereafter. It is supplied as 300 mg vedolizumab in a single dose vial.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to revise existing code J3380 "Injection, vedolizumab, 1 mg", is not approved, because the proposed revision to specify intravenous administration is unnecessary, and does not improve the code. Existing Level II HCPCS modifier JA "administered intravenously" is available to be appended to this code if warranted, to specify intravenous route of administration. As there is no currently licensed subcutaneous route of administration for this product, a distinction based on a different route of administration is not indicated. If a subcutaneous route of administration is subsequently cleared, existing modifier JB "administered subcutaneously" is available to be appended to this code if warranted.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

We received no comments at CMS' HCPCS Public Meeting regarding this application, or in response to our published Preliminary recommendation.

FINAL DECISION

This request to revise existing code J3380 "Injection, vedolizumab, 1 mg", is not approved, because the proposed revision to specify intravenous administration is unnecessary, and does not improve the code. Existing Level II HCPCS modifier JA "administered intravenously" is available to be appended to this code if warranted, to specify intravenous route of administration.

As there is no currently licensed subcutaneous route of administration for this product, a distinction based on a different route of administration is not indicated. If a subcutaneous route of administration is subsequently cleared, existing modifier JB "administered subcutaneously" is available to be appended to this code if warranted.