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

Wednesday, May 17, 2017

This HCPCS Code Application Summary document includes a summary of each HCPCS code application discussed at the May 17, 2017 HCPCS Public Meeting for Drugs, Drugs, Biologicals and Radiopharmaceuticals and Radiologic Imaging Agents. HCPCS code applications are presented within the summary document in the same sequence as the Agenda for this Public Meeting. Each individual summary includes: the application number, topic; background/discussion of the applicant's request; CMS' published preliminary HCPCS coding recommendation; CMS' published preliminary Medicare payment recommendation; a summary of comments offered on behalf of each applicant at CMS' HCPCS public meeting in response to our preliminary recommendations; and CMS' final HCPCS coding decision. We publish a separate HCPCS Code Application Summary document for each HCPCS Public Meeting held. This is one of a series of five HCPCS Code Application Summaries for CMS' 2017-2018 HCPCS coding cycle.

Introduction and Overview

Approximately 65 people attended. The agenda included 13 items.

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

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

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

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

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

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

The latest information on the process for developing agendas and speaker lists for the public meetings, as well as the Guidelines for Proceedings at these CMS' Public Meetings, can be found on the CMS HCPCS web site, specifically at: www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.html. In addition, the standard application format for requesting a modification to the HCPCS Level II Code Set, along with instructions for completion and background information regarding the HCPCS Level II coding process is available at: http://cms.gov/medhcpcsgeninfo/01_overview.asp#TopOfPage.
The application form is updated annually and posted on the CMS HCPSC website sometime in the summer. A decision tree, outlining CMS' decision-making criteria is also available at: HCPCS Decision Tree - cms.gov.

May 17, 2017

Agenda Item # 1

Application# 17.020

TOPIC

Request to establish a new Level II HCPCS code to identify riboflavin 5'-phosphate in 20% dextran ophthalmic solution, Trade Names: Photrexa, Viscous/Photrexa.

Applicant's suggested language: JXXXX "Riboflavin 5'-phosphate, 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 for corneal collagen cross-linking (CXL) to treat serious thinning of the cornea in keratoconus and corneal ectasia. Photrexa is used with Avedro's KXL system and it is administered as riboflavin 5'-phosphate ophthalmic solution (with dextran) and if needed, riboflavin 5'-phosphate ophthalmic solution (without dextran).

In the CXL procedure, Photrexa is administered by the physician through glass syringes, and installed topically on the eye, one drop every 2 minutes for 30 minutes. If corneal thickness is less than 400 microns, 2 drops of Photrexa (without dextran), are administered every 5 to 10 seconds to increase corneal thickness to at least 400 microns. Irradiation is then performed for 30 minutes during which Photrexa (with dextran) is administered every two minutes. Photrexa is supplied for single patient use as follows: with dextran in a 3 mL syringe containing 1.46 mg/mL riboflavin 5'-phosphate in 20% dextran ophthalmic solution; and without dextran in a 3mL syringe containing 1.46 mg/mL riboflavin 5'-phosphate ophthalmic solution.

The applicant comments that a new code is warranted because 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.

PRELIMINARY HCPCS CODING RECOMMENDATION

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

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision. The speaker requested that CMS reverse its preliminary decision and create a J code for Photrexa. The speaker stated four reasons to establish a code: 1) the drug is used about 50% of the time in a physician's office, and is not paid as part of the corneal cross-linking procedure during which it is used; 2) CMS has previously established J codes for other drops used during eye procedures; 3) Photrexa is not included in CPT procedure code; and 4) Photrexa is an orphan drug. The speaker also indicated it is used for two orphan indications and that it is the only FDA approved drug used to perform corneal cross-linking procedures. Therefore, a unique code is needed for separate billing and payment in that setting.

FINAL DECISION:

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

May 17, 2017

Agenda Item # 2

Application# 17.058

TOPIC

Repeat request to establish a new level II HCPCS code to identify phenylephrine and ketorolac injection 1%/0.3%, Trade Name: Omidria.

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

BACKGROUND

The Omeros Corporation submitted a request to establish a new Level II HCPCS code to identify Omidria. Omidria is an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor that is indicated for maintaining pupil size by preventing intraoperative miosis; and reducing postoperative pain. According to the applicant, Omidria is added to standard irrigation solution used during cataract surgery and intraocular lens (IOL) replacement procedures.

Omidria is a solution concentrate containing 12.4 mg/mL of phenylephrine hydrochloride and 4.24 mg/mL ketorolac tromethamine. It is supplied in a 5 mL, single-patient-use vial, containing 4 mL of sterile solution. For administration to patients undergoing cataract surgery or IOL replacement, 4 mL of Omidria is diluted in 500 mL of ophthalmic irrigation solution. Irrigation solution is used as needed during the surgical procedure. Omidria can be used in ophthalmologists' offices during, for example, refractive lens exchange and phakic IOL surgery and, potentially, to treat uveitis, acute iritis, and iridocyclitis.

The applicant comments that a unique J-code for Omidria is needed in order "to avoid both payer and provider confusion, to allow physician's offices and the ASCs to submit primary claims so that they can electronically 'crosswalk' to the secondary/supplemental payers". In addition, "2017 is the final year of transitional pass-through payment for Omidria. C9447 (Injection, phenylephrine and ketorolac, 4 mL vial), which was assigned for the purpose of pass-through payments, will no longer serve that purpose and that makes it critical for a new unique code to be assigned in 2018".

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need to establish a new code for Omidria was not identified by Medicare, Medicaid, or the Private Insurance Sector. Existing code C9447 "Injection, Phenylephrine and ketorolac, 4 mL vial" is available for assignment by insurers if they deem appropriate, to report use of Omidria in a hospital outpatient setting.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision. The speaker requested that CMS reverse its preliminary decision and create a J code for Omidria. The speaker stated the lack of a J code has produced electronic claims and payment processing issues for commercial payers unable to process C9947. The primary speaker also stated commercial payers, and approximately 22 state Medicaid programs, have informed providers that they cannot process claims billed under a C code and require claims to be billed under a J code.

FINAL DECISION:

A national program operating need to establish a code for Omidria was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance, contact the entity in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

May 17, 2017

Agenda Item # 3

Application# 17.046

TOPIC

Request to establish a new Level II HCPCS code to identify Optiray 350 ioversol injection 74%, Optiray 320 ioversol injection 68% and Optiray 300 ioversol injection 64%; Trade Name: Optiray™ Ultraject™ provided in a Prefilled Syringe®.

Applicant's suggested language: JXXXX "ioversol injection pre-filled syringe"

BACKGROUND

Guerbet, LLC, submitted a request to establish a new Level II HCPCS code to identify Optiray™ Ultraject™ Prefilled Syringe®. Optiray is a radiopaque contrast agent primarily used to visualize vessels and changes in tissues on radiography and CT. Optiray 300, 320, and 350 are indicated in adults for contrast enhanced computed tomographic imaging of the head and body, intravenous excretory urography, intravenous digital subtraction angiography and venography. Optiray 350 is indicated in children for angiocardiography. Head imaging, scanning can be performed immediately after completion of the intravenous administration. For body imaging Optiray can be administered by bolus injection, by rapid infusion, or by a combination of both.

Optiray 350, 320, and 300 are supplied in single-use, hand-held, power injector and RFID tagged injector syringes in a variety of fill volumes. Optirary 350 contains 741 mg. Ioversol per mL. Optiray 320 contains 678 mg. Ivoersol per mL. Optiray 300 contains 636 mg. Ioversol per mL, and Optiray 240 contains 509 mg Ioversol per mL. The applicant comments that there is no existing HCPCS code assigned to the Optiray™ Ultraject™ Prefilled Syringe "and billing just the product in a syringe does not account for the syringe itself."

The applicant also commented that "the syringes can be billed with not-otherwise classified (NOC) HCPCS code J3490 (Drug Not Otherwise Classified), but it would be a better tracking and reporting mechanism to have a distinct HCPCS code for the drug in a prefilled delivery. The use of HCPCS code J3490 does not allow concise tracking of utilization and often results in underpayment of the drug."

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Optiray Ultraject Prefilled Syringe has not been approved. A separate code is not necessary to describe ioversol in a pre-filled syringe. Existing code Q9967 "Low osmolar contrast material, 300-399 mg/ml iodine concentration, per ml" adequately describes Optiray 300, Optiray 320, and Optiray 350; and it is available for assignment by insurers if they deem appropriate. Existing code Q9966 "Low osmolar contrast material, 200-299 mg/mL iodine concentration, per mL" adequately describes

Optiray 240 and is available for assignment by insurers if they deem appropriate. Separate reporting of the syringe for additional payment may be considered redundant and inappropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION:

This request to establish a new Level II HCPCS code to separately identify the Optiray Ultraject Prefilled Syringe has not been approved. A separate code is not necessary to describe ioversol in a pre-filled syringe. Existing code Q9967 "Low osmolar contrast material, 300-399 mg/ml iodine concentration, per ml" adequately describes Optiray 300, Optiray 320, and Optiray 350; and it is available for assignment by insurers if they deem appropriate. Existing code Q9966 "Low osmolar contrast material, 200-299 mg/mL iodine concentration, per mL" adequately describes Optiray 240 and is available for assignment by insurers if they deem appropriate. Separate reporting of the syringe for additional payment may be considered redundant and inappropriate.

Application# 17.067

TOPIC

Request to establish a new level II HCPCS code to identify the Optiray Ultraject Prefilled Syringe with Radio Frequency Identification (RFID) technology.

Applicant's suggested language: AXXXX - Ioversol injection Radio Frequency Identification (RFID) pre-filled syringe.

BACKGROUND

Guerbet LLC submitted a request to establish a new level II HCPCS code to identify Optiray Ultraject Prefilled Syringe with Radio Frequency Identification (RFID) technology. According to the applicant, Optiray (Ioversol injection) formulations are sterile, nonpyrogenic, aqueous solutions that are intended for intravascular administration as diagnostic radiopaque media.

RFID is a technology that captures, stores, and transmits data between the injector and the syringe using RFID tags or transponders. Ultraject RFID prefilled syringes help reduce patients' risks of cross-infection or mis-administration, reduces healthcare professionals' exposure to avoidable risks due to top glass breakage and needles, and provides a sterile, closed, single-used system for every patient. The RFID pre-filled syringe is placed into a power injector so the contrast media can be injected into a patient before a CT scan, administering a patient dose of contrast in a disposable system.

Optiray 300, 320, and 350 are indicated in adults for contrast enhanced computed tomographic imaging of the head and body, intravenous excretory urography, intravenous digital subtraction angiography and venography. Optiray 350 is indicated in children for angiocardiography.

The applicant comments that a new code is warranted because there is currently no code assigned to Optiray Ultraject Prefilled Syringe with Radio Frequency Identification (RFID) technology, and that billing simply the product in the syringe does not account for the syringe. Moreover, patient-ready, pre-filled syringes with RFID are costlier than the drug in either a single-use vial or a multi-pack or a non-tagged RFID pre-filled syringe. The applicant suggested that the syringes can be billed with the NOC HCPCS code J3490, but it would be a better tracking and reporting mechanism to have a distinct HCPCS code for the drug in a pre-filled RFID delivery. The use of J3490 does not allow concise tracking of utilization and often results in underpayment for the drug.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify the Optiray Ultraject Prefilled Syringe with Radio Frequency Identification (RFID) technology has not been approved. Existing code Q9967 "Low osmolar contrast material, 300-399 mg/ml iodine concentration, per ml" adequately describes Optiray 300, Optiray 320, and Optiray 350; and it is available for

assignment by insurers if they deem appropriate. Separate reporting of the syringe for additional payment may be considered redundant and inappropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION:

This request to establish a new Level II HCPCS code to separately identify the Optiray Ultraject Prefilled Syringe with Radio Frequency Identification (RFID) technology has not been approved. Existing code Q9967 "Low osmolar contrast material, 300-399 mg/ml iodine concentration, per ml" adequately describes Optiray 300, Optiray 320, and Optiray 350; and it is available for assignment by insurers if they deem appropriate. Separate reporting of the syringe for additional payment may be considered redundant and inappropriate.

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Agenda Item # 4

Application# 17.004

TOPIC

Request to revise existing Level II HCPCS code J7328 which currently reads: "Hyaluronan or derivative, gel-syn, for intra-articular injection, 0.1 mg, to reflect the products' new name: Trade Name: GELSYN-3.

Applicant's suggested language: "Hyaluronan or Derivative, GELSYN-3, for intra-articular injection, 0.1 mg"

BACKGROUND

On behalf of IBSA Institute Biochimique SA and Bioventus LLC; IBSA Pharma, Inc., submitted a request to revise the text of existing code J7328 to reflect the product's new Trade Name: GELSYN-3. According to the applicant, the classification, composition, dosage and administration is unchanged for this product. Only the product name has changed. The product was never sold in the US under the previous name Gel-Syn.

According to the applicant, GELSYN-3 is a sodium hyaluronate that is administered by injection for the treatment of pain in patients with osteoarthritis of the knee who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen). The injected hyaluronic acid lubricates the osteoarthritic knee to enhance viscoelasticity, thereby augmenting the knee's natural shock absorbing capability and promoting pain relief. GELSYN-3 is supplied in a sterile, 2.1 mL syringe containing 16.8 mg of hyaluronic acid for injection. It is administered in a sequence of up to three injections.

The applicant comments that the requested code revision is necessary in order to accurately identify the product by its current Brand Name, and to prevent billing confusion and inaccurate claims.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing HCPCS code J7328, which currently reads, "Hyaluronan or derivative, gel-syn, for intra-articular injection, 0.1 mg", to instead read, "Hyaluronan or Derivative, GELSYN-3, for intra-articular injection, 0.1 mg." Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

FINAL DECISION:

Revise existing HCPCS code J7328, which currently reads, "Hyaluronan or derivative, gel-syn, for intra-articular injection, 0.1 mg", to instead read, "Hyaluronan or Derivative, GELSYN-3, for intra-articular injection, 0.1 mg."

May 17, 2017

Agenda Item # 5

Application# 17.038

TOPIC

Request to discontinue existing Level II HCPCS code J7321 which currently reads: "Hyaluronan or derivative, hyalgan or supartz, for intra-articular injection, per dose", and replace it with 2 new codes; one each to identify Hyalgan and Supartz, with their respective (and different) dose descriptors.

Applicant's suggested language: JXXX1 "Hyaluronan or derivative, Hyalgan®, for intra-articular injection, per 20 mg dose".

Applicant's suggested language: JXXX2 "Hyaluronan or derivative, Supartz, for intra-articular injection, per 25 mg dose".

BACKGROUND

Fidia Pharma USA Inc., submitted a request to discontinue existing Level II HCPCS code J7321 "Hyaluronan or derivative, Hyalgan® or Supartz, for intra-articular injection, per dose and replace it with 2 new codes: one each to separately identify Hyalgan and Supartz, with their respective (and different) dose descriptors.

According to the applicant, code J7321 which Hyalgan® shares with Supartz does not adequately distinguish Hyalgan.

The applicant comments that Hyalgan and Supartz sharing a code is not appropriate because the 2 products are "pharmaceutically and therapeutically different", "with different clinical outcomes". The applicant suggests the following therapeutic distinctions: (1) one study showed a higher adverse reaction rate for Adant, when compared with Hyalgan and Adant is "molecularly equivalent to Supartz; (2) " Hyalgen has superior disease modifying activity based on animal and preclinical testing"; (3) "Hyalgan has a lower coefficient of friction and Sommerfeld number compared to Supartz; (4) "Hyalgan is the only approved Hyaluronate (HA) compared to NSAIDS, another accepted method of treatment"; (5) Hyalgan is the only HA with 30 months of data for safety and effectiveness of repeat treatment"; (6) Hyalgan has cost effectiveness data for almost 4 years"; (7) the dosages are different (Hyalgan 20 mg., Supartz 25 mg); (8) the number of doses in the treatment protocol is different between the two products; and (9) the associated costs are different.

The applicant comments that Hyalgan should be distinguished from Supartz via coding, based on the product and outcome differences detailed above.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify Hyalgan has not been approved. Existing code J7321 "Hyaluronan or derivative, hyalgan or supartz, for intra-articular injection, per dose" adequately describes Hyalgan and is available for assignment by insurers if they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation, stating that there is a significant therapeutic distinction between Hyalgan and Supartz; that the existing codes do not differentiate between the products; and that there are differences in dosing and safety profiles. The speaker reiterated the request for distinct codes for Hyalgan and Supartz.

FINAL DECISION:

This request to discontinue existing level II HCPCS code J7321 which currently reads: "Hyaluronan or derivative, hyalgan or supartz, for intra-articular injection, per dose", and replace it with two new codes; one each to identify Hyalgan, 20 mg and Supartz, 20 mg has not been approved. Code J7321 "Hyaluronan or derivative, hyalgan or supartz, for intra-articular injection, per dose", as revised effective 1/1/2018 to read "Hyaluronan or derivative, hyalgan, Supartz or VISCO-3 for intra-articular injection, per dose" adequately describes the products that are the subject of this request, and is available for assignment by insurers if they deem appropriate.

May 17, 2017

Agenda Item # 6

Application# 17.051

TOPIC

Request to establish a new Level II HCPCS code to identify Sodium Hyaluronate, 25 mg, Trade Name: VISCO-3.

Applicant's suggested language: JXXXX "Hyaluronan or derivative, VISCO-3, for intra-articular injection, per mg".

BACKGROUND

Zimmer Biomet submitted a request to establish a new Level II HCPCS code to identify VISCO-3. According to the applicant, VISCO-3 is a sterile, viscoelastic non-pyrogenic solution of purified, high molecular weight sodium hyaluronate (hyaluronan). It is indicated for the treatment of pain in the osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics.

VISCO-3 is unique in terms of formulation and injection regimen, when compared with other intra-articular hyaluronic acid injections on the market today. VISCO-3 supplements the naturally occurring hyaluronic acid in the synovial fluid within the joint capsule of the affected knee to provide cushioning and lubrication to the joint, which have been reduced due to the degradation of the joint caused by the osteoarthritis.

VISCO-3 is administered via intra-articular injection by a healthcare practitioner into the joint capsule of the affected knee to provide cushioning and lubrication to the joint. It is supplied in prefilled 2.5mL syringes, which contain 25.0 mg sodium hyaluronate and 21.25 sodium chloride. A treatment regime of VISCO-3 consists of injections of 2.5 mL once per week for 3 weeks (a total of 3 injections).

The applicant suggests that VISCO-3 meets the definition of "single source drug or biological" under SSA 1847 A (c) (6) (D); and as such it qualifies for separate Medicare pricing; and a new unique code should be established to facilitate separate pricing for VISCO-3. The applicant further stated that "until such time as a more specific HCPCS code is created and assigned to VISCO-3, it will be billed with HCPCS code J3490-Unclassified Drugs".

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing HCPCS code J7321, which currently reads, "Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose", to instead read, "Hyaluronan or derivative, Hyalgan, Supartz or VISCO-3, for intra-articular injection, per dose". Effective 1/1/18. Revised

code J7321 adequately describes VISCO-3. Use of code J3490 to report VISCO-3 is not appropriate unless specifically assigned in insurer policy.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary decision. The speaker requested that CMS reverse its preliminary decision and create a J code to identify VISCO-3. The speaker stated the establishment of a unique J code distinct from existing code J7321 would separately identify VISCO-3 for the purposes of administering rebating and medical management of VISCO-3 and other similar injectables that are commonly paid under the medical benefit of a health plan.

FINAL DECISION:

Revise existing HCPCS code J7321, which currently reads, "Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose", to instead read, "Hyaluronan or derivative, Hyalgan, Supartz or VISCO-3, for intra-articular injection, per dose". Revised code J7321 adequately describes VISCO-3. Use of code J3490 to report VISCO-3 is not appropriate unless specifically assigned in insurer policy.

May 17, 2017

Agenda Item # 7

Application# 17.029

TOPIC

Request to establish a new Level II HCPCS code to identify recombinant FACTOR VIII blood clotting factor, Trade Name: AFSTYLA .

Applicant's suggested language: J7XXX, "Injection, Factor VIII single chain (Recombinant), per IU".

BACKGROUND

CSL Behring, LLC submitted a request to establish a new Level II HCPCS code to identify AFSTYLA. According to the applicant, AFSTYLA is a recombinant FACTOR VIII blood clotting factor indicated for on-demand treatment and control of bleeding episodes and routine prophylaxis to prevent or reduce frequency of bleeding episodes, and perioperative management of bleeding. AFSTYLA is a recombinant protein that replaces the missing Coagulation Factor VIII needed for effective hemostasis.

According to the applicant, AFSTYLA is the first and only recombinant fusion protein expressed as a single chain Factor VIII molecule with a truncated B-domain that allows for a covalent link between heavy and light chains; thereby keeping the molecule in a single chain from resulting in increased stability and increased von Willebrand Factor (vWF) affinity. The recommended dose of AFSTYLA for routine prophylaxis for adults and children 12 years of age and older is 20 to 50 IU per kg administered 2 to 3 times weekly. More frequent or higher doses may be required in children 12 years of age to account for the higher clearance in children of this age group. AFSTYLA is packaged in single use vials with Sterile Water for Injection, USP (2.5mL for reconstitution of 250, 500 or 1000 IU or 5mL for reconstitution of 2000 or 3000 IU), one Mix2Vial and filter transfer set and one alcohol swab.

The applicant comments that no existing HCPCS codes adequately describe AFSTYLA and that a unique single source biologic drug under SSA 1847 A (c) (6) (D), and as such qualifies for separate Medicare pricing, and a specific code is needed in order to facilitate separate pricing.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, factor viii (antihemophilic factor, recombinant), (afstyla), 1 i.u.". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION:

Establish J7210, "Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u."

May 17, 2017

Agenda Item # 8

Application# 17.030

TOPIC

Request to establish a new Level II HCPCS code to identify an Antihemophilic Factor, (Recombinant), Trade Name: KOVALTRY.

Applicant's suggested language: “JXXXX Antihemophilic Factor (Recombinant), per IU".

BACKGROUND

Bayer Healthcare Pharmaceuticals, Inc., submitted a request to establish a new Level II HCPCS code to identify KOVALTRY. According to the applicant, it is a recombinant, human DNA sequence derived, full length factor VIII concentrate. KOVALTRY temporarily replaces missing coagulation factor VIII needed for effective hemostasis in patients with congenital hemophilia A. KOVALTRY is administered via intravenous infusion. For control of bleeding episodes and perioperative management, dosing is based on patient weight with different formulas for calculating doses. For routine prophylaxis, the recommended dose for adults and adolescents is 20 to 40 IU/kg 2 or 3 times per week; and for children 12 years of age or younger, 25 to 50 IU/kg twice per week; 3 times per week or every other day. KOVALTRY is supplied as lyophized powder in single-use vials containing nominally 250, 500, 1000, 2000 or 3000 IU. Each vial contains the labeled amount of recombinant Factor VIII in IU. Kovaltry is supplied with BIO-SET vial adapter, a needleless self-contained reconstitution system and a prefilled diluent syringe containing sterile water for injection.

The applicant comments that a new code is warranted because no other products have the same combination of molecular description, dosing range, and dosing frequency. In addition, the applicant comments that existing codes do not adequately describe KOVALTRY because it is the only unmodified, full length recombinant factor VIII indicated for as few as 2 infusions per week for routine prophylaxis.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "injection, factor viii, (Antihemophilic Factor, recombinant), (kovaltry), 1 i.u”. Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION:

Establish J7211, "injection, factor viii, (Antihemophilic Factor, recombinant), (kovaltry), 1 i.u."

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Agenda Item # 9

Application# 17.001

TOPIC

Request to establish a new Level II HCPCS code to identify injection, infliximab, biosimilar, Trade Name: Inflectra.

Applicant's suggested language: JXXXX "Injection, Infliximab, Biosimilar, 10 mg".

BACKGROUND

Hospira, a Pfizer Company, submitted a request to establish a new Level II HCPCS code to identify Inflectra. According to the applicant, Inflectra is a tumor necrosis factor (TNF) blocker administered by intravenous infusion, indicated for the treatment of Crohn's disease, pediatric Crohn's disease, Ulcerative colitis, rheumatoid arthritis in combination with methotrexate, ankylosing spondylitis, psoriatic arthritis, or plaque arthritis. Infliximab neutralizes the biological activity of TNF-alpha (TNFx) by binding with high affinity to the soluble and transmembrane forms of TNFx with its receptors.

Inflectra is supplied in single-dose vials containing 100 mg of infliximab-dyyb for final reconstitution volume of 10 mL. Inflectra is administered by intravenous infusion over a period of not less than 2 hours. The recommended dose of Inflectra is 5mg/kg given as an intravenous induction regimen at 0, 2, and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter for the treatment of adults with moderately to severely active Crohn's disease or fistulizing Crohn's disease. For adult patients who respond and then lose their response, consideration may be given to treatment with 10 mg/kg. Patients who do not respond by week 14 are unlikely to respond with continued dosing and consideration should be given to discontinuing Inflectra in these patients.

The applicant comments that a new code is warranted because there are no product-specific codes to bill payers for Inflectra (inliximab biosimilar).

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new Level II HCPCS code to separately identify Inflectra (infliximab biosimilar) has not been approved. Existing code Q5102 "Injection, infliximab, biosimilar, 10 mg" together with existing ZB modifier "Pfizer/Hospira" adequately describes Inflectra (infliximab biosimilar) and are 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 decision.

FINAL DECISION:

This request to establish a new Level II HCPCS code to separately identify Inflectra (infliximab biosimilar) has not been approved. Existing code Q5102 "Injection, infliximab, biosimilar, 10 mg" together with existing ZB modifier "Pfizer/Hospira" adequately describes Inflectra (infliximab biosimilar) and are available for assignment by insurers if they deem appropriate.

May 17, 2017

Agenda Item # 10

Application# 17.003

TOPIC

Request to establish a new Level II HCPCS code to identify Nusinersen, Trade Name: (SPINRAZA™).

Applicant's suggested language: "Injection, nusinersen for intrathecal use, SPINRAZA, 1 mg"

BACKGROUND

Biogen, Inc. submitted a request to establish a new Level II HCPCS code to identify SPINRAZA. According to the applicant, SPINRAZA is an antisense oligonucleotide indicated for use to treat Spinal Muscular Atrophy (SMA). SMA is a disease characterized by loss of motor neurons in the spinal cord and lower brain stem, severe and progressive muscular atrophy and weakness and, in some cases, paralysis and difficulty performing basic life functions (e.g., breathing). SMA is caused by mutations in the chromosome 5q resulting in Survival Motor Neuron (SMN) protein deficiency. SPINRAZA alters the splicing of pre-messenger ribonucleic acid from the Survival of Motor Neuron 2 gene, increasing production of fully functional SMN protein in patients with SMA.

The recommended dose in patients older than 2 years of age is 12 mg (5mL). For infants 2 years of age or younger, the volume of injection should be adjusted based on age.

SPINRAZA is administered by intrathecal injection and supplied as a 12mg/5mL (2.4mg/mL solution in a single-dose vial. Treatment is initiated with 4 loading doses provided on Days 0,14, 28 and 63; thereafter, a maintenance dose is provided every 4 months.

The applicant comments that a new code is needed in order to facilitate separate pricing for SPINRAZA, as a new molecular entity and a "single source drug or biological."

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "injection, nusinersen, 0.1 mg". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION:

Establish J2326, "injection, nusinersen, 0.1 mg".

May 17, 2017

Agenda Item # 11

Application# 17.049

TOPIC

Request to establish a new Level II HCPCS code to identify a hydrogel wound dressing containing 4% Lidocaine Hydrochloride, Trade Name: Astero.

Applicant's suggested language:

Either AXXXX or JXXXX: "Hydrogel wound dressing containing 4% Lidocaine Hydrochloride, per 1 metered dose"

BACKGROUND

Genesco Laboratories, LLC, submitted a request to establish a new level II HCPCS code to identify Astero. Astero is a medicated hydrogel wound dressing containing Lidocaine Hydrochloride 4% (a topical anesthetic).

According to the applicant, "Astero is specifically formulated to create a moist healing environment, which promotes granulation, epithelialization, and autolytic debridement, while providing prolonged anesthesia of the wound thereby lessening the need for systematic pain medications including opiate based drugs." It is a "topically applied prescription product approved for treatment of painful wounds". It is indicated for stage I-IV pressure ulcers, venous stasis ulcers, ulcerations caused by mixed vascular etiologies, diabetic skin ulcers, first and second degree burns, post-surgical incisions as well as, cuts and abrasions. Astero is supplied as a Metered Dose pump in an airless 30 ml container that delivers 0.25 ml per pump and can be self-administered.

The applicant comments that "the only HCPCS drug code that can be suggested at the present time is J3490, "Unclassified drug" and that existing code C9285 is for intravenous infusion of lidocaine. The applicant seeks either a "J" code for the hydrogel/lidocaine combination, or an "A" code for the wound dressing.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new HCPCS code to identify Astero. For coding guidance, contact the individual insurance contractor in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION:

A national program operating need to establish a code to identify Astero was not identified by Medicare, Medicaid or the Private Insurance Sector. For coding guidance contact the individual insurance contractor in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

May 17, 2017

Agenda Item # 12

Application# 17.062

TOPIC

Request for a new Level II HCPCS code to identify 0.5 mg lidocaine hydrochloride monohydrate powder, intradermal injection system, Trade Name: Zingo.

Applicant's suggested language, JXXXX "Injection, lidocaine HCl, 0.5 mg".

BACKGROUND

Powder Pharmaceuticals Inc., has requested a new Level II HCPCS code to identify Zingo.

According to the applicant, Zingo contains lidocaine, an amide local anesthetic indicated for use on intact skin to provide local analgesia prior to venipuncture or peripheral intravenous cannulation in children 3-18 years of age and prior to venipuncture in adults.

Lidocaine blocks sodium ion channels required for the initiation and conduction of neuronal impulses, resulting in local anesthesia. This product is a needle-free powder intradermal injection delivery system that directly delivers the lidocaine HCL powder through the skin into the dermis utilizing pressurized helium. It provides local dermal analgesia within 1-3 minutes of application. Analgesia diminishes within 10 minutes of treatment. The dosage is 0.5 mg lidocaine hydrochloride monohydrate powder. The product is supplied in a single-use device packaged in an individual clear pouch. Twelve pouched devices are placed in labeled cartons. The product is supplied in a single-use device packaged in an individual clear pouch. Twelve pouched devices are placed in labeled cartons.

The applicant comments that the only existing code for Lidocaine HCl is for intravenous administration. A new code is needed to identify a powder intradermal injection system.

PRELIMINARY HCPCS CODING RECOMMENDATION

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to separately identify the Zingo system. Zingo, if used, would be included in the procedure or in the supply allowance for the infusion pump. For coding guidance, contact the individual insurance contractor in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION:

A national program operating need was not identified by Medicare, Medicaid, or the private insurance sector to establish a new Level II HCPCS code to separately identify the Zingo system. Zingo, if used, would be included in the procedure or in the supply allowance for the infusion pump. For coding guidance, contact the individual insurance contractor in whose jurisdiction a claim would be filed. For Medicaid, contact the Medicaid Agency in the state in which a claim would be filed. For private insurance, contact the individual insurance contractor. For Medicare, contact the Medicare contractor.

May 17, 2017

Agenda Item # 13

Application# 17.056

TOPIC

Request to establish a new Level II HCPCS code to identify etelcalcetide for IV administration, Trade Name: Parsabiv.

Applicant's suggested language: JXXXX, "Injection, etelcalcetide, per 2.5 mg".

BACKGROUND

Amgen, Inc. submitted a request to establish a new Level II HCPCS code to identify Parsabiv. According to the applicant, Parsabiv is a calcium-sensing receptor agonist indicated for the treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on hemodialysis. It is a synthetic peptide calcimimetic agent that allosterically modulates the calcium-sensing receptor (CaSR). Etelcalcetide binds to the CaSR and enhances activation of the receptor by extracellular calcium. Activation of the CaSR on parathyroid chief cells decreases parathyroid hormone (PTH) secretion.

The recommended starting dose is 5 mg administered by intravenous (IV) bolus injection three times per week at the end of the hemodialysis treatment. Dose may be increased in 2.5 mg or 5 mg increments no more frequently than every 4 weeks. Parsabiv maintenance dosage should be individualized and determined by titration based on PTH and corrected serum calcium response, with a dose range between 2.5 - 15 mg.

Parsabiv is supplied in single-use vials in the following strengths/sizes: 2.5 mg/0.5 mL (NDC 55513-740-10); 5 mg/1 mL (NDC 55513-751-10); and 10 mg/2 mL (NDC 55513-742-10).

The applicant comments that a new HCPCS code is warranted because no existing code describes Parsabiv. The applicant also commented that a new code is needed in order to facilitate timely implementation of the Transitional Drug Add-on Payment Adjustment (TDAPA) to CMS' End Stage Renal Disease Prospective Payment System (ESRD PPS).

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection, etelcalcetide, 0.1 mg". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker requested sooner implementation of the proposed new code.

FINAL DECISION:

Establish J0606, "Injection, etelcalcetide, 0.1 mg"

Application# 17.057

TOPIC

Request to establish a new Level II HCPCS code to identify cinacalcet, Trade Name: Sensipar.

Applicant's suggested language: JXXXX, "Cinacalcet, oral, 30 mg".

BACKGROUND

Amgen, Inc. submitted a request to establish a new Level II HCPCS code to identify Sensipar. According to the applicant, Sensipar is a calcium-sensing receptor agonist indicated for the treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on dialysis. Sensipar is also indicated for the treatment of hypercalcemia in adult patients with parathyroid carcinoma and adult patients with primary hyperparathyroidism (HPT) for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.

Sensipar is a calcimimetic agent that increases the sensitivity of the calcium-sensing receptor to activation by extracellular calcium. Cinacalcet, the active ingredient in Sensipar, directly lowers parathyroid hormone (PTH) levels by increasing the sensitivity of the calcium-sensing receptor to extracellular calcium.

Sensipar is administered orally. The recommended starting dose is 30 mg once daily, and dose titrations are recommended no more frequently than every two to four weeks through sequential doses of 30, 60, 90, 120, and 180 mg once daily as necessary to achieve targeted intact PTH levels.

Sensipar is supplied in tablet form in three different strengths (packaged in bottles of 30 tablets):

30 mg tablets (NDC 55513-073-30)

60 mg tablets (NDC 55513-074-30)

90 mg tablets (NDC 55513-075-30)

The applicant comments that a new code will be needed in order to facilitate payment for Sensipar under Medicare Part B when CMS implements the Transitional Drug Add-on Payment Adjustment (TDAPA) to CMS' End-Stage Renal Disease Prospective Payment System (ESRD PPS).

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "cinacalcet, oral, 1 mg, (for ESRD on dialysis)". Effective 1/1/18.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker requested sooner implementation of the proposed new code.

FINAL DECISION:

Establish J0604, "cinacalcet, oral, 1 mg, (for ESRD on dialysis)".