Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Drugs/Biologicals, Radiopharmaceuticals/Radiologic Imaging Agents
Tuesday, May 17, 2016 9:00 am – 5:00 pm

CMS Auditorium
7500 Security Boulevard
Baltimore (Woodlawn), Maryland 21244-1850

8:15 a.m. Arrival and sign-in

9:00 a.m. Welcome
Background and purpose of meeting
Meeting Format and Ground Rules

For each agenda item, a written overview of the request and CMS' preliminary coding decision is provided. Preliminary decisions are not final or binding upon any payer, and are subject to change. Meeting participants will hear presentations about each agenda item from the registered primary speaker and other speakers (if any). Presentations will be followed by an opportunity for questions regarding that particular agenda item. The public meetings provide an opportunity for the general public to provide additional input related to requests to modify the HCPCS code set. Final decisions are not made at the public meetings. Applicants will be notified of final decisions in November.

The agenda includes a summary of each HCPCS code application on the agenda. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

AGENDA ITEM #1
Attachment# 16.001
Request to assign injectable hyaluronan, GenVisc 850®, to existing code J7321 “Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose”.

AGENDA ITEM #2
Attachment# 16.003
Request to establish a new level II HCPCS code to identify a recombinant coagulation factor, albumin fusion protein, Trade Name: IDELVION.

AGENDA ITEM #3
Attachment# 16.007
Request to establish a new level II HCPCS code to identify a viscoelastic hyaluronan, Trade Name: HYMOVIS®.

AGENDA ITEM #4
Attachment# 16.022
Request to establish a new level II HCPCS code to identify an Antihemophilic Factor, (Recombinant), PEGylated, Trade Name: ADYNOVATE.

Attachment# 16.023
Request to establish a new Level II HCPCS code to identify von Willebrand Factor (Recombinant), Trade Name: VONVENDI.

AGENDA ITEM #5
Attachment# 16.004
Request to establish a new level II HCPCS code to identify an oral antiemetic agent, (rolapitant), Trade Name: VARUBI™.

AGENDA ITEM #6
Attachment# 16.005
Request to establish a new level II HCPCS code to identify an interleukin-5 antagonist monoclonal antibody (mepolizumab), Trade Name: NUCALA.

AGENDA ITEM #7
Attachment# 16.006
Request to establish a new level II HCPCS code to identify a genetically modified oncolytic viral therapy (talimogene laherparepvec), Trade Name: IMLYGIC™.

AGENDA ITEM #8
Attachment# 16.009
Request to establish a new level II HCPCS code to identify an interleukin-5 antagonist monoclonal antibody, reslizumab, Trade Name: Cinqair.

AGENDA ITEM #9
Attachment# 16.010
Request to establish new Level II HCPCS code to identify a SLAMF7-directed immunostimulatory antibody (elotuzumab), Trade Name: Empliciti.

AGENDA ITEM #10
Attachment# 16.011
Request to establish a new Level II HCPCS code to identify a non-steroidal anti-inflammatory (NSAID), diclofenac sodium, Trade Name: dyloject.

AGENDA ITEM #11
Attachment# 16.014
Request to establish a new Level II HCPCS code to identify an atypical antipsychotic drug, aripiprazole lauroxil, Trade Name: Aristada.

AGENDA ITEM #12
Attachment# 16.025
Request to establish new Level II HCPCS code to identify a 5-FU toxicity antidote, (uridine triacetate), Trade Name: VISTOGARD.

AGENDA ITEM #13
Attachment# 16.026
Request to establish a new Level II HCPCS code to identify an alkylating drug, bendamustine hydrochloride, Trade Name: Bendeka.

AGENDA ITEM #14
Attachment# 16.027
Request to establish a new Level II HCPCS code to identify an alkylating drug (trabectedin), Trade Name: YONDELIS.

HCPCS Public Meeting Agenda Item #1
May 17, 2016

Attachment# 16.001

Topic/Issue:

Request to assign injectable hyaluronan, GenVisc 850®, to existing code J7321 "Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose".

Background/Discussion:

OrthogenRX, Inc. submitted a "request for administrative action to determine that GenVisc 850 is adequately described by existing code J7321" "Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose", which currently identifies Supartz® and Hyalgan®.

According to the applicant, GenVisc 850, an injectable sodium hyaluronate, is indicated for the treatment of pain in osteoarthritis of the knee for patients who have failed to respond adequately to conservative non-pharmacological therapy and simple analgesics (e.g., acetaminophen). While the mechanism of action of sodium hyaluronate products is not fully understood, the applicant suggests that they increase viscoelasticity and lubrication, coat nociceptors, inhibit inflammation, and promote endogenous HA production in the synovium.

GenVisc 850 is administered by injection into the intra-articular space of the knee joint by a healthcare professional. A treatment cycle consists of three or five injections of 2.5ml, 10mg/ml intra-articular knee injections, given at weekly intervals. GenVisc 850a is supplied in a 3 ml glass syringe. Each 2.5 ml of GenVisc 850 contains 10 mg/ml of sodium hyaluronate dissolved into a physiological saline (1.0% solution).

The applicant comments that the inclusion of GenVisc 850 into the current HCPCS code J7321 is warranted because GenVisc 850 was developed to be equivalent in composition, molecular characteristics, dosing, dosage form, and clinical performance to Supartz.

Preliminary Decision:

1) Existing code Q9980 "Hyaluronan or derivative, genvisc 850, for intra-articular injection, 1mg" adequately describes the product that is the subject of this request. It is available for assignment by insurers if they deem appropriate.
2) Discontinue Q9980. Effective 12/31/16.
3) Establish JXXXX "Hyaluronan or derivative, genvisc 850, for intra-articular injection, 1mg" to replace Q9980. Effective 1/1/17.

HCPCS Public Meeting Agenda Item #2
May 17, 2016

Attachment# 16.003

Topic/Issue:

Request to establish a new level II HCPCS code to identify a recombinant coagulation factor, albumin fusion protein, Trade Name: IDELVION.

Applicant's suggested language: "J7xxx – Injection, Coagulation Factor IX, (Recombinant), Albumin fusion protein, IDELVION™ per each IU."

Background/Discussion:

CSL Behring submitted a request to establish a code for IDELVION. According to the applicant, IDELVION is indicated for routine prophylaxis to prevent or reduce bleeding episodes: and control and prevent bleeding in the perioperative setting. IDELVION is indicated for use by both pediatric and adult patients with hemophilia B (congenital Factor IX deficiency).

IDELVION is administered intravenously at a rate not to exceed 10 mL per minute. For use in the control and prevention of bleeding episodes and perioperative management, dosage and duration of treatment depends on the severity of the Factor IX deficiency, the location and extent of bleeding, and the patient's clinical condition, age and recovery of Factor IX. For use as a routine prophylaxis for patients ≥ 12 years of age, the recommended dose is 25/40 IU/kg body weight every 7 days. Patients who are well-controlled on this regimen may be switched to a 14-dat interval at 50-75 IU/kg body weight. For use as a routine prophylaxis in patients < 12 years of age, the recommended dose is 40-55 IU/kg body weight every 7 days.

IDELVION is available as a lyophilized powder in single-use vials, containing 250, 500, 1000, or 2000 IUs.

The applicant commentsedhat a new code is warranted because IDELVION is the first and only recombinant fusion protein linking coagulation factor IX with albumin to replace the missing coagulation Factor IX needed for hemostasis, and provides for longer dose regimens. No other marketed products have the same active ingredient category or generic name.

Preliminary Decision:

1) Establish JXXXX, "injection, factor IX, albumin fusion protein, (recombinant), idelvion, 1 i.u.".
2) Revise existing code J7201, which currently reads, "Injection, factor ix, fc fusion protein (recombinant), per iu", to instead read, "Injection, factor IX, fc fusion protein, (recombinant), Alprolix, 1 i.u.".

HCPCS Public Meeting Agenda Item #3
May 17, 2016

Attachment# 16.007

Topic/Issue:

Request to establish a new level II HCPCS code to identify a viscoelastic hyaluronan, Trade Name: HYMOVIS®.

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

Background/Discussion:

Fidia Pharma USA, Inc. submitted a request to code HYMOVIS®. According to the applicant, HYMOVIS is indicated for osteoarthritis patients who have failed to respond adequately to conservative non-pharmacologic therapy or simple analgesics.

HYMOVIS is intended to be injected into the knee joint space. HYMOVIS is supplied in a set of two single-use, 5 mL syringes, each pre-filled with 3 mL (8 mg/mL) HYMOVIS.

The applicant commented that a new code is warranted because HYMOVIS is unique as compared to other viscosupplement products. HYMOVIS differs from hyaluronic acid derivatives due to its molecular structure. HYMOVIS is the only non-chemically crosslinked hyaluronan-based viscosupplement showing gel-like behavior with the capability to recover its viscoelastic properties after several cycles of mechanical stress.

Preliminary Decision:

1) Establish JXXXX "Hyaluronan or derivative, HYMOVIS, for intra-articular injection, 1 mg."
2) Newly established code C9471 "Hymovis, 1 mg" is available for assignment by insurers if they deem appropriate, to report use in a HOPPS setting.

HCPCS Public Meeting Agenda Item #4
May 17, 2016

Attachment# 16.022

Topic/Issue:

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

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

Background/Discussion:

Baxalta US, Inc. submitted a request to establish a new level II HCPCS code to identify ADYNOVATE. According to the applicant, ADYNOVATE is a human antihemophilic factor for on-demand treatment and control of bleeding episodes and routine prophylaxis to reduce the frequency of bleeding episodes. ADYNOVATE temporarily replaces missing coagulation factor VIII needed for effective hemostasis in patients with congenital hemophilia A. ADYNOVATE exhibits an extended terminal half-life through pegylation of the parent molecule, ADVATE, which reduces binding to the physiological factor VIII clearance receptor (LRP1).

ADYNOVATE is indicated in adolescent and adult patients (12 years and older) with hemophilia A (congenital factor VIII deficiency). It is not indicated for the treatment of von Willebrand disease.

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

For on-demand treatment and control of bleeding episodes:

- Estimated Increment of Factor VIII (IU/dL or % of normal) = [Total Dose (IU)/body weight (kg)] x 2 (IU/dL per IU/kg)
- Dose (IU) = Body Weight (kg) x Desired factor VIII Rise (IU/dL or % of Normal) x 0.5 (IU/kg per IU/dL)

For routine prophylaxis:

- Administer 40-50 IU per kg body weight, twice per week.

ADYNOVATE is supplied as lyophilized powder in single-use vials, containing nominally (approximately) 250, 500, 1000, or 2000 international units (IU) of factor VIII potency, a diluent vial containing 5 mL of sterile Water for Injection (sWFI), and a BAXJECT II Hi-Flow Needless Transfer Device.

The applicant commented that a new code is warranted because no current HCPCS code adequately describes ADYNOVATE.

Preliminary Decision:

1) Establish JXXXX “Injection, factor VIII (Antihemophilic Factor Recombinant), PEGylated, 1 I.U.”
2) Existing code C9137 “Injection, factor VIII (Antihemophilic Factor Recombinant), PEGylated, 1 I.U.” is available for assignment by insurers if they deem appropriate, to report use in a HOPPS setting.

Attachment# 16.023

Topic/Issue:

Request to establish a new Level II HCPCS code to identify von Willebrand Factor (Recombinant), Trade Name: VONVENDI.

Applicant's suggested language: "JXXXX - von Willebrand factor (Recombinant) (VONVENDI), per IU".

Background/Discussion:

Baxalta US, Inc. submitted a request to code VONVENDI. According to the applicant, VONVENDI is a von Willebrand Factor (VWF), indicated for on-demand treatment and control of bleeding episodes in adults (age 18 and older) diagnosed with von Willebrand disease. In patients with von Willebrand disease, VONVENDI acts, first, to promote hemostasis by mediating platelet adhesion to damaged vascular sub-endothelial matrix (e.g. collagen) and platelet aggregation; and second, VONVENDI acts as a carrier protein for factor VIII, protecting it from rapid proteolysis. The adhesive activity of VWF depends on the size of its multimers, with large multimers being the most effective in supporting interactions with collagen and platelet receptors. The binding capacity and affinity of VONVENDI to factor VIII in plasma is comparable to that of endogenous VWF, allowing for VONVENDI to reduce factor VIII clearance.

VONVENDI is supplied as a lyophilized powder in single-use vials, containing nominally 650 or 1300 international units VWF:RCo. VONVENDI is packaged with Sterile Water for Injection (sWFI) and one Mix2Vial reconstitution device.

Once reconstituted, VONVENDI is administered via intravenous infusion. Doses are measured in international units (IUs) and are determined based on patient weight and taking into account severity, site of bleeding, and medical history of the patient. For a minor hemorrhagic event (e.g., readily managed epistaxis, oral bleeding, menorrhagia), the initial dose is 40 to 50 IU/kg, and subsequent dose is 40 to 50 IU/kg every 8 to 24 hours (as clinically required). For major hemorrhagic events (e.g., severe of refractory epistaxis, menorrhagia, GI bleeding, CNS trauma, hemarthrosis, or traumatic hemorrhage) the initial dose is 50 to 80 IU/kg, and subsequent dose is 40 to 60 IU/kg every 8 to 24 hours for approximately 2-3 days (as clinically required).

The applicant commented that a new code is warranted because no current HCPCS code adequately describes VONVENDI.

Preliminary Decision:

Establish JXXXX “Injection, von willebrand factor complex (recombinant), (Vonvendi), 1 i.u. vwf:rc.”

HCPCS Public Meeting Agenda Item #5
May 17, 2016

Attachment# 16.004

Topic/Issue:

Request to establish a new level II HCPCS code to identify an oral antiemetic agent, (rolapitant), Trade Name: VARUBI™.

Applicant's suggested language: "JXXXX – rolapitant, per 180 mg"

Background/Discussion:

TESARO, Inc. submitted a request to code an oral antiemetic agent, VARUBI™. According to the applicant, VARUBI is a substance P/neurokinin 1 (NK-1) receptor antagonist that is indicated—for use in combination with other antiemetic agents in adults—for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, chemotherapy regimens that are highly emetogenic. VARUBI's active ingredient is rolapitant (VARUBI, TESARO).

VARUBI is indicated for use in combination with other antiemetic agents in adults. VARUBI is contraindicated in patients receiving thioridazine.

VARUBI is administered orally. The recommended dosage is 180 mg. It is supplied as two 90mg tablets as one set. It is taken approximately 1-2 hours prior to chemotherapy in combination with IV or oral corticosteroid (dexamethasone) plus an IV or oral 5-HT3 receptor antagonist, which provides protection for patients from delayed chemotherapy-induced nausea and vomiting (CINV) for the entire duration of the 5 day post-chemotherapy risk period.

The applicant commented that a new code is warranted because VARUBI is not specifically identified in the existing code set, and miscellaneous codes would not allow for precise tracking of utilization and may result in underpayment.

Preliminary Decision:

1) Newly established code Q9981 "Rolapitant, oral, 1mg", effective 7/1/16, adequately identifies VARUBI.
2) Discontinue Q9981, effective 12/31/16.
3) Establish JXXXX "Rolapitant, oral, 1mg", effective 1/1/17.

HCPCS Public Meeting Agenda Item #6
May 17, 2016

Attachment# 16.005

Topic/Issue:

Request to establish a new level II HCPCS code to identify an interleukin-5 antagonist monoclonal antibody (mepolizumab), Trade Name: NUCALA.

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

Background/Discussion:

GlaxoSmithKline submitted a request to establish a new level II HCPCS code to identify NUCALA (mepolizumab). According to the applicant, Mepolizumab is a humanized IL-5 antagonist monoclonal antibody. Mepolizumab is produced by recombinant DNA technology in Chinese hamster ovary cells. NUCALA is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, with eosinophilic phenotype. NUCALA is not indicated for treatment of other eosinophilic conditions, nor is it indicated for the relief of acute bronchospasm.

The recommended dose of NUCULA is 100mg, to be administered once every 4 weeks by subcutaneous injections into the upper arm, thigh, or abdomen; or status asthmaticus. It is supplied as 100mg lyophilized powder in a single-use vial.

The applicant comments that GlaxoSmithKline's NUCALA is a biologic that represents a new chemical entity approved by the FDA with no substitutions possible by existing FDA-approved drugs. There are no other drugs marketed with the same active ingredient category/generic name of mepolizumab/NUCALA. Therefore, no codes currently exist to adequately represent mepolizumab.

Preliminary Decision:

1) Existing code C9473 "Injection, mepolizumab, 1 mg" is available for assignment by insurers if they deem appropriate, to report use in a HOPPS setting.
2) Establish JXXXX, Injection, mepolizumab, 1mg., effective 1/1/17.

HCPCS Public Meeting Agenda Item #7
May 17, 2016

Attachment# 16.006

Topic/Issue:

Request to establish a new level II HCPCS code to identify a genetically modified oncolytic viral therapy (talimogene laherparepvec), Trade Name: IMLYGIC™.

Applicant's suggested language: "JXXXX, injection, talimogene laherparepvec, per 1 million plaque forming units".

Background/Discussion:

Amgen submitted a request to code IMLYGIC™. According to the applicant, IMLYGIC is a genetically modified oncolytic viral therapy indicated for the local treatment of unresectable cutaneous, subcutaneous and nodal lesions in patients with melanoma recurrent after initial surgery.

IMLYGIC is administered by a healthcare professional via injection into cutaneous, subcutaneous, and/or nodal lesions with or without ultrasound guidance. There are two concentrations of the product: 10^6 (1 million) PFU/mL; and 10^8 (100 million) PFU/mL concentration for all subsequent doses. The volume of the injection depends on the size of the lesions injected, and multiple lesions may be injected. Total injection volume for each treatment should not exceed 4 mL. For initial treatment, the largest lesion is injected first. The practitioner prioritizes remaining lesions based on size. The next injection, three weeks after initial treatment, should not exceed 4 mL, and may be administered to previously injected or uninjected lesions. All subsequent treatments should be spaced two weeks apart, and not exceed 4 mL.

IMLYGIC has not been shown to improve overall survival or have an effect on visceral metastases.

The applicant comments that a new code is warranted because there is no permanent national HCPCS code that adequately describes this product.

Preliminary Decision:

Establish J9XXX “injection, talimogene laherparepvec, per 1 million plaque forming units.”

HCPCS Public Meeting Agenda Item #8
May 17, 2016

Attachment# 16.009

Topic/Issue:

Request to establish a new level II HCPCS code to identify an interleukin-5 antagonist monoclonal antibody, reslizumab, Trade Name: Cinqair.

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

Background/Discussion:

Teva Pharmaceuticals submitted a request to code Cinqair. According to the applicant, Cinqair is indicated for use as an add-on treatment in patients with severe asthma aged 18 years and older, and with an eosinophilia phenotype.

Cinqair is a humanized IgG4k monoclonal antibody that binds to human interleukin-5. Cinqair is produced by recombinant DNA technology in a mammalian cell expression system. Cinqair is indicated for the treatment of asthma in adults and adolescents (12 years of age and above).

The recommended dosage regimen is 3mg/kg once every 4 weeks. Cinqair is supplied in 100mg/mL single-use 10mL vials. Cinqair should be administered via 20-50 minute IV infusion in a healthcare setting by a healthcare professional prepared to manage anaphylaxis that could be life-threatening. Patients should be observed for an appropriate period of time after Cinqair infusion.

The applicant comments that a new code is warranted because no existing code describes Cinqair, and because it is a single source drug/biologic with no therapeutic equivalent.

Preliminary Decision:

Establish "JXXXX, Injection, reslizumab, 1mg."

HCPCS Public Meeting Agenda Item #9
May 17, 2016

Attachment# 16.010

Topic/Issue:

Request to establish new Level II HCPCS code to identify a SLAMF7-directed immunostimulatory antibody (elotuzumab), Trade Name: Empliciti.

Applicant's suggested language: "J9XXX – Injection, elotuzumab, 1mg."

Background/Discussion:

Bristol-Myers Squibb submitted a request to code Empliciti (elotuzumab). According to the applicant, Empliciti is a humanized recombinant monoclonal antibody, directed to SLAMF7, a cell surface glycoprotein. Empliciti directly activates Natural Killer cells through both the SLAMF7 pathway and Fc receptors. Empliciti also targets SLAMF7 on myeloma cells and facilitates the interaction with Natural Killer cells to mediate the killing of myeloma cells through antibody-dependent cellular cytotoxicity (ADCC). Empliciti is indicated in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma in patients who have received one to three prior therapies.

The recommended dose for Empliciti is 10mg/kg administered intravenously every week for the first two cycles and every 2 weeks thereafter, until disease progression or unacceptable toxicity. Empliciti is administered in conjunction with the recommended dosing of lenalidomide and low-dose dexamethasone.

Empliciti is supplied as a lyophilized powder in 300mg vials and 400 mg vials.

The applicants comments that a new code is warranted because there are no existing codes that adequately describe Empliciti. Empliciti is a novel biologic approved via a new BLA. No other products are identified by this trade name or are marketed under the same active ingredient category/generic name.

Preliminary Decision:

Establish J9XXX "Injection, elotuzumab, 1mg."

HCPCS Public Meeting Agenda Item #10

May 17, 2016

Attachment# 16.011

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a non-steroidal anti-inflammatory drug (NSAID), diclofenac sodium, Trade Name: Dyloject.

Applicant's suggested language: "JXXXX, Injection, diclofenac sodium, 37.5 mg".

Background/Discussion:

Hospira, a Pfizer Company, submitted a request to code Dyloject. According to the applicant, Dyloject is an injectable NSAID analgesic. It is indicated for use in adults for the management of mild-to-moderate pain as well as for the management of moderate-to-severe pain alone or in combination with opioid analgesics.

The active ingredient in Dyloject, diclofenac sodium, is an NSAID that exhibits anti-inflammatory analgesic and antipyretic activities in animal models. The mechanism of action, like that of other NSAIDs, is not completely understood but may involve inhibition of the cyclooxygenase (COX-1 and COX-2) pathways. Its mechanism may also be related to inhibition of prostaglandin synthetase.

For treatment of acute pain, the recommended dose is 37.5 mg, to be administered by intravenous bolus injection over 15 seconds. Treatment may be repeated every 6 hours, not to exceed 150 mg/day. Patients must be well hydrated before Dyloject administration. Dyloject should be used for the shortest duration consistent with individual patient treatment goals.

Dyloject Injection is available in a single-use 1 mL fill vial containing 37.5 mg/mL.

The applicant comments that a new code is warranted because there is no HCPCS code that adequately reports an intravenous formulation of diclofenac sodium.

Preliminary Decision:

Establish JXXXX “Injection, diclofenac sodium, 0.5 mg.”

HCPCS Public Meeting Agenda Item #11
May 17, 2016

Attachment# 16.014

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an atypical antipsychotic drug, aripiprazole lauroxil, Trade Name: Aristada.

Applicant's suggested language: "JXXXX", Injection, aripiprazole lauroxil, 1mg, for intramuscular use".

Background/Discussion:

Alkermes, Inc. submitted a request to code ARISTADA. According to the applicant, ARISTADA (aripiprazolemarily lauroxil) is a long-acting drug for injection as an anti-psychotic used for the treatment of patients with schizophrenia. It is an extended-release injectable suspension of N-lauroyloxymethyl aripiprazole and a prodrug of aripiprazole.

ARISTADA is supplied in single-use 5 mL pre-filled syringes, containing 441mg, 662 mg, and 882 mg, which corresponds to 300mg, 450mg, and 600 mg of aripiprazole, respectively. ARISTADA is only to be administered by a healthcare professional via intramuscular injection. The 441 mg and 662 mg doses are intended to be administered monthly, and the 882 mg dose may be administered monthly or once every 6 weeks.

The applicant comments that a new code is warranted because there are no existing HCPCS codes to accurately describe ARISTADA.

Preliminary Decision:

1) Establish JXXXX "Injection, aripiprazole lauroxil, 1mg". Effective 1/1/17.
2) Newly established code C9470 "Injection, aripiprazole lauroxil, 1 mg" is available for assignment by insurers if they deem appropriate, to report use in a HOPPS setting.

HCPCS Public Meeting Agenda Item #12
May 17, 2016

Attachment# 16.025

Topic/Issue:

Request to establish new Level II HCPCS code to identify a 5-FU toxicity antidote, (uridine triacetate), Trade Name: VISTOGARD.

Applicant's suggested language: "uridine triacetate, oral granules, 10 grams".

Background/Discussion:

BTG International Inc. submitted a request to code VISTOGARD, manufactured by Wellstat Therapeutics. According to the applicant, VISTOGARD is the first and only antidote indicated for the emergency treatment of adult and pediatric patients following a fluorouracil or capecitabine overdose, regardless of the presence of symptoms, or for treatment of persons who exhibit early-onset, severe or life-threatening toxicity affecting the cardiac of central nervous system, and/or early-onset, usually severe adverse reactions (e.g., gastrointestinal toxicity and/or neutropenia) within 96 hours following the end of fluorouracil or capecitabine administration.

VISTOGARD provides bioavailable uridine, a direct biochemical antagonist of 5-FU toxicity, and is different from uridine due to differences in absorption and catabolism that make VISTOGARD a clinically viable source of uridine as an antidote. In normal cells, VISTOGARD stops cell damage and cell death caused by 5-FU, and counteracts 5-FU toxicity. Treatment should be initiated promptly following recognition of symptoms of serious toxicity, because cell death from 5-FU begins immediately. The efficacy of VISTOGARD initiated more than 96 hours following the end of administration of 5-FU has not been established.

The adult dosage of VISTOGARD is 10 grams orally every 6 hours for 20 doses, without regard to meals. VISTOGARD is supplied as a “course of therapy” carton containing 20 single-use packets; and as a 24-hour carton containing 4 single-use packets. Pediatric dosing is 6.2 grams/m^2 of body surface area. VISTOGARD may also be administered via a nasogastric tube or gastrostomy tube when necessary. Each single-use 10 gram package of VISTOGARD orange-flavored oral granules contains 10 grams of uridine triacetate.

The applicant comments that a new code is warranted for VISTOGARD because no existing HCPCS code describes it, and it “meets the requirements for a claim of significant therapeutic distinction.”

Preliminary Decision:

This request to establish a Level II HCPCS code to separately identify VISTOGARD has not been approved. Level II HCPCS is not the appropriate coding jurisdiction for this product.

HCPCS Public Meeting Agenda Item #13
May 17, 2016

Attachment# 16.026

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an alkylating drug, bendamustine hydrochloride, Trade Name: Bendeka.

Applicant's suggested language: "J9XXX: Injection, bendamustine HCl (Bendeka), low-volume infusion, per 1 mg."

Background/Discussion:

Eagle Pharmaceuticals, Inc. submitted a request to code Bendeka. According to the applicant, Bendeka is a unique bendamustine hydrochloride (HCL) formulation indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) or indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen. Bendeka is a single-source prescription drug that provides physicians with an effective treatment option to deliver bendamustine HCl to patients in a low-volume intravenous infusion.

Bendeka is only prescribed when a diagnosis of CLL, or NHL has been made. Bendeka is provided in a multiple-dose vial containing 100mg/4mL of bendamustine hydrochloride (25mg/mL). The volume needed for a required dose is withdrawn from the multiple-dose vial aseptically and transferred to a 50mL infusion bag.

The applicant comments that a new code is warranted because no existing HCPCS code adequately describes Bendeka.

Preliminary Decision:

This request to establish a new Level II HCPCS code to separately identify Bendeka has not been approved. Existing code J9033 "Injection, bendamustine hcl, 1 mg" adequately describes the product that is the subject of this request.

HCPCS Public Meeting Agenda Item #14
May 17, 2016

Attachment# 16.027

Topic/Issue:

Request to establish a new Level II HCPCS code to identify an alkylating drug (trabectedin), Trade Name: YONDELIS.

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

Background/Discussion:

Janssen Biotech, Inc. submitted a request to establish a new Level II HCPCS code to identify YONDELIS. According to the applicant, YONDELIS is an alkylating drug indicated for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who have received a prior anthracycline-containing regimen. Trabectedin binds guanine residues in the minor groove of DNA, forming adducts and resulting in a bending of the DNA helix towards the major groove. Adduct formation triggers a cascade of events that can affect the subsequent activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in perturbation of the cell cycle and eventual cell death.

YONDELIS is to be administered by a healthcare professional as a 24-hour intravenous infusion, every 21 days (3 weeks) through a central venous line, until disease progression or unacceptable toxicity, in patients with normal bilirubin and AST or ALT $\leq$ 2.5 times the upper limit of normal. This 3 week period is considered a treatment cycle. The recommended dose is 1.5 mg/m^2 BSA.

YONDELIS is supplied as lyophilized powder in single-use vials containing 1mg of trabectedin.

The applicant comments that existing codes do not accurately describe YONDELIS, and a new, unique HCPCS code would facilitate accurate reporting and payment.

Preliminary Decision:

Establish J9XXX “Injection, trabectedin, 0.1 mg.”