

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

**Monday, May 14, 2018**

This HCPCS Code Application Summary document includes a summary of each HCPCS code application discussed at the May 14, 2018 HCPCS Public Meeting for Drugs, Drugs, Biologicals and Radiopharmaceuticals and Radiologic Imaging Agents. HCPCS code applications are presented within the summary document in the same sequence as the Agenda for this Public Meeting. Each individual summary includes: the application number, topic; background/discussion of the applicant's request; CMS' published preliminary HCPCS coding recommendation; CMS' published preliminary Medicare payment recommendation; a summary of comments offered on behalf of each applicant at CMS' HCPCS public meeting in response to our preliminary recommendations; and CMS' final HCPCS coding decision. We publish a separate HCPCS Code Application Summary document for each HCPCS Public Meeting held. This is one of a series of five HCPCS Code Application Summaries for CMS' 2018-2019 HCPCS coding cycle.

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

**Monday, May 14, 2018**

**Agenda Item # 1**

**Application# 18.002**

**TOPIC**

Request to establish a new Level II HCPCS code to identify the amyotrophic lateral sclerosis (ALS) treatment for intravenous use, Trade Name: RADICAVA.

Applicant's suggested language: JXXXX-“edaravone injection, solution, 1 mg.”

**BACKGROUND**

MT Pharma America, Inc. submitted a request to establish a new Level II HCPCS code to identify RADICAVA (edaravone), an injection for intravenous use. According to the applicant, RADICAVA was FDA approved with an Orphan Drug designation as treatment for amyotrophic lateral sclerosis (ALS), a rapidly progressive neurodegenerative disease.

According to the applicant, RADICAVA (edaravone) is hypothesized to chemically reduce oxidative stress by scavenging free radicals and inhibiting peroxidation. In addition, the applicant indicates that RADICAVA (edaravone) is believed to slow functional neuronal deterioration by exerting its inhibitory and neuroprotective effects against the development of oxidative damage to vascular endothelial cells and nerve cells. RADICAVA (edaravone) is the first approved treatment that can either alter the progressive decline in motor function or can improve ALS symptoms. ALS is a progressive and fatal neurodegenerative disease that affects nerve cells in the brain and the spinal cord.

RADICAVA (edaravone) injection is for intravenous use only. The recommended dosage is an intravenous infusion of 60 mg administered over a 60-minute period according to the following schedule: An initial treatment cycle with daily dosing for 14 consecutive days followed by a 14 day drug-free period. Subsequent treatment cycles with daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods. Each 60 mg dose of RADICAVA (edaravone) injection is administered as two consecutive 30 mg IV bags administered over 60 minutes. RADICAVA (edaravone) is supplied as 30/mg/100 mL solution for IV infusion in a single-dose bag. Each carton of RADICAVA (edaravone) contains two single-dose bags, or one daily dose.

The applicant comments that a new code is warranted because there are currently no available codes that describe RADICAVA (edaravone) injection.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish JXXXX, "Injection, edaravone, I mg." Effective 1/1/19.

**SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

There was no primary speaker for this item. No comments were offered at CMS' HCPCS public meeting in response to our preliminary recommendation.

## **FINAL DECISION**

Establish J1301, "Injection, edaravone, 1 mg." Effective 1/1/19.

**Monday, May 14, 2018**

**Agenda Item # 2**

**Application# 18.004**

**TOPIC**

Request to establish a new Level II HCPCS code to identify daunorubicin and cytarabine liposome for intravenous use, Trade Name: VYXEOS.

Applicant's suggested language:"JXXXX-Injection, daunorubicin and cytarabine liposome (VYXEOS), 1mg".

**BACKGROUND**

Jazz Pharmaceuticals, Inc., submitted a request to establish a new Level II HCPCS code to identify VYXEOS. According to the applicant, VYXEOS is indicated for the treatment of adults with newly diagnosed, therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

VYXEOS is combination of a daunorubicin and cytarabine in a 1:5 molar ratio encapsulated in liposomes for intraveneous administration. The ratio has been shown to have synergistic effects on killing leukemia cells in both in vitro and animal models. Danunorubicin expresses antimitotic and cytotoxic activity, which is achieved by forming complexes with DNA, inhibiting topoisomerase II activity, inhibiting DNA polymerase activity, affecting regulation of gene expression, and producing DNA-damaging free radicals. Cytarabine acts primarily through inhibition of DNA polymerase. The mechanism of action for these two drugs delivered to leukemia cells via VYXEOS liposomes is different when compared to conventional free drug dosing of cytarabine and daunorubicin.

The injection is for intravenous use only and is administered as a 90-minute infusion. It is supplied as a lyophilized cake, in a single-dose vial containing 44 mg daunorubicin and 100 mg cytarabine, in cartons containing 2 or 5 single-use vials of VYXEOS. The applicant comments that a new code is warranted for VYXEOS because it is a unique drug that exhibits significant therapeutic distinction partially based on its differentiated mechanism of action.

The applicant further comments that it is the first chemotherapy to demonstrate an overall survival advantage over the standard of care in a Phase 3 randomized study of older adults with newly-diagnosed t-AML-MRC. Additionally, the applicant states a new code would prevent dosing errors and possible confusion with single-agent formulations of daunorubicin and cytarabine.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish JXXXX, "Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine." Effective 1/1/19.

### **SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

There was no primary speaker for this item. Written comments were submitted by the applicant agreeing with CMS' preliminary coding recommendation and indicated that it is important for there to be consistency in the HCPCS nomenclature and billing units as providers transition from C9024 to VYXEOS JXXXX effective 1/1/19.

### **FINAL DECISION**

Establish J9153, "Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine." Effective 1/1/19.

**Monday, May 14, 2018**

**Agenda Item # 3**

**Application# 18.009**

**TOPIC**

Request to establish a new Level II HCPCS code to identify DUROLANE

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

**BACKGROUND**

Bioventus LLC requested to establish a new Level II HCPCS code to identify DUROLANE. According to the applicant, DUROLANE is a clear, transparent, viscous gel of highly purified, stabilized, high molecular weight, non-animal derived sodium hyaluronate derived from bacterial fermentation (*Streptococcus equi*).

DUROLANE is indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacological therapy or simple analgesics such as acetaminophen. Intra-articular injections of exogenous HA, such as DUROLANE, can help to restore viscosity and elasticity, and thereby diminish pain. DUROLANE is administered through a single intra-articular injection (3mL, 20mg/ ml) into the knee joint, by an authorized physician or medical professional. It is supplied in a 3 mL, single use (single-dose) syringe. The needle is not provided.

According to the applicant, no existing codes describe DUROLANE. DUROLANE has a unique gel particle structure and combination of properties, such as volume, HA source, injection regime and duration of effect and hence a new code is warranted.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish JXXXX, "Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg." Effective 1/1/19.

**SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

The primary speaker agreed with the HCPCS preliminary recommendation to establish a J code with the exception that a per dose descriptor be consistent with the established C9465 code and other single-injection hyaluronan acid HCPCS codes. The speaker indicated that this HCPCS nomenclature is recommended to avoid provider confusion and errors in billing unit calculation and claims processing.

**FINAL DECISION**

Establish J7318, "Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg."  
Effective 1/1/19.

**Monday, May 14, 2018**

**Agenda Item # 4**

**Application# 18.017**

**TOPIC**

Request to establish a new Level II HCPCS code to identify a sodium hyaluronate, Trade Name: TriVisc.

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

**BACKGROUND**

OrthogenRx, Inc. submitted a request to establish a new Level II HCPCS code to identify a sterile, non-pyrogenic solution of purified, high molecular weight sodium hyaluronate, TriVisc. According to the applicant, TriVisc is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics. The exact mechanism of action has not been identified. It is hypothesized that TriVisc injections into the knee are helpful in restoring the synovial fluid to a healthier state and may also have anti-inflammatory and direct analgesic effects as well.

Each TriVisc treatment consists of three 2.5 ml, 10mg/ml injections, given at weekly intervals. TriVisc is injected in the patient's affected knee by a certified healthcare professional. TriVisc is supplied in a 3ml glass syringe. Each 2.5 ml of TriVisc contains 10mg/ml of sodium hyaluronate dissolved into a physiological saline (1.0% solution). It is packaged as a sterile syringe injectable.

According to the applicant there are no existing codes that accurately describe TriVisc. TriVisc is not identical to any other HA product in dosage form and indication for use. The applicant commented that TriVisc was approved under its own and independent PMA, therefore a new and unique HCPCS code is required.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish JXXXX- "Hyaluronan or derivative, TriVisc, for intra-articular injection, 1 mg." Effective 1/01/19.

**SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

The primary speaker agrees with CMS' preliminary recommendation to establish a J code for TriVisc and that intra-articular HA therapy is a good clinical choice for Medicare patients to treat osteoarthritis knee pain.

## **FINAL DECISION**

Establish J7329 "Hyaluronan or derivative, TriVisc, for intra-articular injection, 1 mg." Effective 1/01/19.

**Monday, May 14, 2018**

**Agenda Item # 5**

**Application# 18.006**

**TOPIC**

Request to establish a new Level II HCPCS code to identify the C1 Esterase Inhibitor, Subcutaneous (Human), Trade Name: HAEGARDA.

Applicant's suggested language: JXXXX- "Injection, C1 Esterase Inhibitor (human), (haegarda), per 100 IU."

**BACKGROUND**

CSL Behring, LLC. submitted a request to establish a new Level II HCPCS code to identify HAEGARDA. According to the applicant, HAEGARDA is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) (C1-INH) indicated for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients.

HAEGARDA is prepared from large pools of human plasma from U.S. donors. The manufacturing process for HAEGARDA includes multiple steps that reduce the risk of virus transmission. C1-INH has an important inhibiting potential on several of the major human cascade systems, including the complement, fibrinolytic, and coagulation systems. Regulation of these systems is performed through the formation of complexes between the protease and the inhibitor, resulting in inactivation, consumption, and subsequent replacement of any dysfunctional C1-INH.

HAEGARDA is intended for self-administration at a dose of 60 International Units (IU) per kg body weight by subcutaneous injection twice weekly (every 3 or 4 days). HAEGARDA is available as a lyophilized powder supplied in single-use vials containing either 2000 or 3000 IU of C1-INH. HAEGARDA is packaged with Sterile Water for Injection, USP (4mL for reconstitution of 2000 IU or 6 mL for reconstitution of 3000 IU) and one Mix2Vial filter transfer set. HAEGARDA is prescribed for use in all settings which include physician's offices, hospital inpatient or outpatient facilities, and patient's home by patient or health care provider.

The applicant comments that a new code is warranted for HAEGARDA consistent with the agency's implementation of section 1847 of the Social Security Act (SSA), which requires that separate payment be made for "single source drugs and biologicals" first sold in the US on or after 10/01/2003.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish JXXXX, "Injection, C-1 esterase inhibitor (human), (haegarda), 10 units." Effective 1/1/19.

## **SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

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

## **FINAL DECISION**

Establish J0599, "Injection, C-1 esterase inhibitor (human), (haegarda), 10 units." Effective 1/1/19.

**Monday, May 14, 2018**

**Agenda Item # 6**

**Application# 18.005**

**TOPIC**

Request to revise the dose descriptor of Level II HCPCS code J9300 "Injection, gemtuzumab ozogamicin, 5 mg" from 5 mg to 0.1 mg. Trade Name: MYLOTARG.

Applicant's suggested language: "Injection, gemtuzumab ozogamicin, 0.1 mg".

**BACKGROUND**

Pfizer, Inc., submitted a request to revise the dose descriptor of existing Level II HCPCS code J9300 from 5 mg to 1 mg. According to the applicant, MYLOTARG injection is an antibody-drug conjugate composed of the cytotoxic agent calicheamicin, attached to a monoclonal antibody (mAB) targeting CD33, an antigen expressed on the surface of myeloblasts in up to 90% of patients with acute myeloid leukemia (AML).

MYLOTARG is indicated for both the treatment of newly-diagnosed CD33-positive AML in adults and for treatment of relapsed or refractory CD33-positive AML in adults and pediatric patients two years and older. It is administered by IV infusion over 2 hours. Dosing depends on the treatment regimen, cycle of therapy, and the treatment day. MYLOTARG is supplied as a lyophilized cake or powder in a 4.5 mg single-dose vial.

The applicant comments that a revised dose descriptor is warranted because the current 5 mg descriptor does not align with MYLOTARG's 4.5 mg vial size.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Existing code J9203 "Injection, gemtuzumab ozogamicin, 0.1 mg" established 1/1/18, is available for assignment by insurers if they deem appropriate.

Code J9300 was discontinued 12/31/17.

**SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

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

**FINAL DECISION**

Existing code J9203 "Injection, gemtuzumab ozogamicin, 0.1 mg" established 1/1/18, is available for assignment by insurers if they deem appropriate.

Code J9300 was discontinued 12/31/17.

**Monday, May 14, 2018**

**Agenda Item # 7**

**Application# 18.015**

**TOPIC**

Request to establish a new Level II HCPCS code to identify inotuzumab ozogamicin for injection, Trade Name: BESPONSA.

Applicant's suggested language: JXXXX- "Injection, inotuzumab ozogamicin, 0.1 mg."

**BACKGROUND**

Pfizer, Inc., submitted a request to establish a new Level II HCPCS code to identify BESPONSA (inotuzumab ozogamicin) for injection, a new physician administered biological. According to the applicant, BESPONSA is an antibody-drug conjugate (ADC) composed of a monoclonal antibody (mAb) targeting CD22, a cell surface antigen expressed on cancer cells in almost all B-cell precursor acute lymphoblastic leukemia (ALL) patients, linked to a cytotoxic agent. When BESPONSA binds to the CD22 antigen or B-cells, it is internalized into the cell, where the cytotoxic agent calicheamicin is released, and causing cell death. It is indicated for the treatment of adults with relapsed or refractory B-cell precursor ALL.

The recommended dosage per administration is 0.5 mg/m<sup>2</sup> or 0.8 mg/m<sup>2</sup>, depending on the treatment day and the patient's response to treatment. It is administered by IV infusion over 1 hr. BESPONSA is supplied as 0.9 mg lyophilized powder in a single-dose vial for reconstitution and further dilution. The applicant comments that a new code is warranted because there are currently no permanent HCPCS codes that describes BESPONSA; although has been assigned a temporary C-code for Medicare hospital outpatient use (C9028- Injection, inotuzumab ozogamicin, 0.1 mg).

The applicant indicates that a unique permanent code is needed to recognize the approval of BESPONSA under a unique BLA to ensure ASP based payment in the physician's office.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish JXXXX, "Injection, inotuzumab ozogamicin, 0.1 mg." Effective 1/1/19.

**SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

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

**FINAL DECISION**

Establish J9229, "Injection, inotuzumab ozogamicin, 0.1 mg." Effective 1/1/19.

**Monday, May 14, 2018**

**Agenda Item # 8**

**Application# 18.022**

**TOPIC**

Request to establish a new Level II HCPCS code to identify rolapitant, Trade Name: Varubi injectable emulsion, for intravenous use.

Applicant's suggested language: JXXXX "rolapitant, per 166.5 mg."

**BACKGROUND**

TESARO, Inc., submitted a request to establish a new Level II HCPCS code to identify rolapitant injectable emulsion for intravenous use. According to the applicant, rolapitant is a substance P/neurokinin 1 (NK-1) receptor antagonist indicated with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy.

A single dose of VARUBI can remain active for up to 120 hours after administration and has a plasma half-life of 7 days. Rolapitant is administered in combination with a 5-HT3 receptor antagonist and dexamethasone by intravenous infusion. The 30-minute infusion occurs within two hours before chemotherapy is administered. The recommended frequency of administration is once before each chemotherapy cycle, no more than once every two weeks. Rolapitant injectable emulsion is supplied as 166.5 mg/92.5 mL (1.8 mg/mL) of rolapitant in a single-dose vial. Rolapitant is also available in 90 mg tablets.

The applicant comments that a new code is warranted because there is no existing code that is "therapeutically and pharmaceutically equivalent" to the injectable emulsion form of rolapitant.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish JXXXX, "Injection, rolapitant, 0.5 mg." Effective 1/1/19

**SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

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

**FINAL DECISION**

Establish J2797, "Injection, rolapitant, 0.5 mg." Effective 1/1/19

**Monday, May 14, 2018**

**Agenda Item # 9**

**Application# 18.016**

**TOPIC**

Request to establish a new Level II HCPCS code to identify cerliponase alfa, Trade Name: BRINEURA.

Applicant's suggested language: JXXXX- "Injection, cerliponase alfa for intraventricular infusion, 1 mg."

**BACKGROUND**

BioMarin Pharmaceutical, Inc., submitted a request to establish a new Level II HCPCS code to identify BRINEURA. BRINEURA is indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency. CLN2 is an inherited, autosomal recessive disease primarily impacting children ages 2-4 years old. The rare but rapidly progressing neurodegenerative disease is caused by genetic mutations in the TPP1 enzyme. The applicant claims that BRINEURA is the only FDA-approved product that treats CLN2 disease.

BRINEURA should be administered by, or under the direction of a physician knowledgeable in intraventricular administration. It is administered to the cerebrospinal fluid (CSF) in the brain via a surgically implanted reservoir and catheter. The recommended dosage is 300 mg every other week as an intraventricular infusion followed by infusion of intraventricular electrolytes over approximately 4.5 hours. A single 300 mg dose of BRINEURA is supplied in a carton containing two 5 mL vials (150mg/5ml each) and 1 vial of intraventricular electrolytes injection, (5ml in a single-dose vial). An administration supply kit containing disposable components is sold separately.

The applicant comments that a new code is warranted in order to ensure tracking and proper billing; streamline claim processing; and facilitate improved Medicaid rebate collections. In addition, a unique code would facilitate separate payment under Medicare Part B as authorized through SSA section 1847 A(b)(4).

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish JXXXX, "Injection, cerliponase alfa, 1 mg." Effective 1/01/19.

**SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

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

**FINAL DECISION**

Establish J0567, “Injection, cerliponase alfa, 1 mg.” Effective 1/01/19.

**Monday, May 14, 2018**

**Agenda Item # 10**

**Application# 18.030**

**TOPIC**

Request to establish a new Level II HCPCS code to identify benralizumab, Trade Name: FASENRA.

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

**BACKGROUND**

AstraZeneca Pharmaceuticals LP submitted a request to establish a new Level II HCPCS code to identify benralizumab, trade name FASENRA. FASENRA is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa) indicated for the add-on maintenance treatment of patients with severe asthma, aged 12 years and older and with an eosinophilic phenotype.

FASENRA binds to the alpha subunit of the human interleukin-5 (IL-5) receptor with high affinity and specificity. The IL-5 receptor is expressed on the surface of eosinophils and basophils. In an in vitro setting, the absence of fucose in the Fc domain of benralizumab facilitates binding to Fc<sub>γ</sub>RIII receptors on immune effector cells, such as natural killer (NK) cells, leading to apoptosis of eosinophils and basophils through antibody-dependent cell-mediated cytotoxicity (ADCC). The recommended dose of FASENRA is 30 mg every 4 weeks for the first 3 doses, followed by a 30 mg dose once every 8 weeks thereafter. FASENRA is administered as a subcutaneous injection and, according to the applicant, should be administered by a health care professional. It is supplied as a 30 mg/mL solution in a single-dose prefilled syringe.

The applicant comments that a new code is warranted because there are no HCPCS codes to describe FASENRA's active ingredient, benralizumab.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

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

**SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

There was no primary speaker for this item. Written comments were submitted by the applicant supporting CMS' preliminary recommendation and that they would like to see CMS finalize this preliminary recommendation.

**FINAL DECISION**

Establish J0517,” Injection, benralizumab, 1 mg.” Effective 1/1/19.

**Monday, May 14, 2018**

**Agenda Item # 11**

**Application# 18.003**

**TOPIC**

Request to establish a new Level II HCPCS code to identify rituximab and hyaluronidase human, Trade Name: RITUXAN HYCELA.

Applicant's suggested language: JXXXX-“Subcutaneous Injection, rituximab and hyaluronidase human, 100 mg.”

**BACKGROUND**

Genentech, Inc. submitted a request to establish a new Level II HCPCS code to identify rituximab and hyaluronidase human. According to the applicant, RITUXAN HYCELA is a combination of rituximab, a CD20-directed cytolytic antibody, and hyaluronidase human, an endoglycosidase. RITUXIMAB is a monoclonal antibody that targets the CD20 antigen expressed on the surface of pre-B and mature B-lymphocytes. Upon binding to CD20, rituximab mediates B-cell lysis. Possible mechanisms of cell lysis include complement dependent cytotoxicity (CDC) and antibody dependent cell mediated cytotoxicity (ADCC). Recombinant human hyaluronidase is a transiently active, locally acting permeation enhancing enzyme. The mode of action of hyaluronidases is to locally depolymerize the substrate, hyaluronan (hyaluronic acid, HA), at the site of the injection in the subcutis, thereby facilitating drug delivery into the systemic circulation.

RITUXAN HYCELA is indicated for the treatment, of adult patients with Follicular Lymphoma (FL), Diffuse Large B-cell Lymphoma (DLBCL), and Chronic Lymphocytic Leukemia (CLL). RITUXAN HYCELA is administered by a healthcare professional as a subcutaneous injection as a flat dose of either 1,400 mg or 1,600 mg per injection. RITUXAN HYCELA is supplied as 1,400 mg rituximab and 23,400 units hyaluronidase human per 11.7 mL in a 15 mL single dose vial; and as 1,600 mg rituximab and 26,800 units hyaluronidase human per 13.4 mL in a 20 mL single-dose vial.

The applicant comments that a new code is warranted because there is no unique Level II HCPCS code to describe RITUXAN HYCELA.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

- 1) Establish JXXXX, "Injection, rituximab, and hyaluronidase, 10 mg." Effective 1/1/19.
- 2) Discontinue J9310, "Injection, rituximab, 100mg." Effective 12/31/18.
- 3) Establish JXXXX "Injection, rituximab 10 mg." Effective 1/1/19.

## **SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

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

## **FINAL DECISION**

- 1) Establish J9311, "Injection, rituximab 10 mg and hyaluronidase." Effective 1/1/19.
- 2) Discontinue J9310, "Injection, rituximab, 100mg." Effective 1/1/19.
- 3) Establish J9312 "Injection, rituximab 10 mg." Effective 1/1/19.

**Monday, May 14, 2018**

**Agenda Item # 12**

**Application# 18.008**

**TOPIC**

Request to establish a new Level II HCPCS code to identify triamcinolone acetonide extended-release injectable suspension, Trade Name: ZILRETTA.

Applicant's suggested language: "JXXXX, triamcinolone acetonide extended-release injectable suspension (ZILRETTA), 1mg, for intra-articular injection."

**BACKGROUND**

Flexion Therapeutics, Inc. submitted a request to establish a new Level II HCPCS code to identify ZILRETTA. According to the applicant, ZILRETTA is an extended-release synthetic corticosteroid indicated as an intra-articular injection for the management of osteoarthritis pain in the knee. According to the applicant, Triamcinolone acetonide is a corticosteroid with both anti-inflammatory and immunomodulating properties. It binds to and activates the glucocorticoid receptor, leading to activation of anti-inflammatory transcription factors such as lipocortins and inhibition of inflammatory transduction pathways to blocking the release of anachidonic acid to prevent the synthesis of prostaglandins and leukotrienes.

ZILRETTA is an injectable suspension that delivers 32 mg of triamcinolone acetonide. It is supplied as a single-dose kit containing one vial of ZILRETTA microsphere powder, one vial of 5mL diluent and vial adapter. ZILRETTA is not intended for repeat administration. The efficacy and safety of repeat administration of ZILRETTA for the management of osteoarthritis pain of the knee have not been evaluated. ZILRETTA is for intra-articular use only. It is not suitable for use in small joints, such as the hand. The efficacy and safety of ZILRETTA for management of osteoarthritis pain of the shoulder and hip have not been evaluated.

The applicant is making a claim of significant therapeutic distinction between ZILRETTA, Kenalog-40, and Triesence for intravitreal injection, on the basis that ZILRETTA is not interchangeable with other formulations of injectable triamcinolone acetonide. The applicant also claims ZILRETTA has a substantially different product design developed specifically for intra-articulation administration that incorporates different material not used by existing products. Studies comparing use of these products were not provided.

The applicant comments that a new code is warranted because existing codes do not adequately describe ZILRETTA. The applicant also notes that a new code would ease the administrative burden associated with miscellaneous coding and would allow payers to capture important product-specific data. Existing miscellaneous codes such as J3490 and C9399 do not permit the appropriate identification of ZILRETTA since it is an extended-release microsphere formulation supplied in a kit and must be prepared using the diluent supplied.

## **PRELIMINARY HCPCS CODING RECOMMENDATION**

1. Established Q9993, "Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg." Effective 7/1/18.
2. Discontinue Q9993 code effective 12/31/18.
3. Establish JXXXX, "Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg." Effective 1/1/19.

## **SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

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

## **FINAL DECISION**

1. Established Q9993, "Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg." Effective 7/1/18.
2. Discontinue Q9993 code effective 1/1/19.
3. Establish J3304, "Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg." Effective 1/1/19.

**Monday, May 14, 2018**

**Agenda Item # 13**

**Application# 18.011**

**TOPIC**

Request to establish a new Level II HCPCS code to identify durvalumab, Trade Name: IMFINZI.

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

**BACKGROUND**

AstraZeneca Pharmaceuticals LP submitted a request to establish a new HCPCS code in the J9XXX section of the HCPCS to identify IMFINZI, a human programmed death ligand-1 (PD-L1) blocking antibody indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma whose disease has progressed during or after one standard platinum-based regimen, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

Expression of programmed cell ligand-1 (PD-L1) can be induced by inflammatory signals (e.g., IFN-gamma) and can be expressed on both tumor cells and tumor-associated immune cells in the tumor macro-environment. PD-L1 blocks T-cell function and activation through interaction with PD-1 and CD80 (B7.1). By binding to its receptors, PD-L1, reduces cytotoxic T-cell activity, proliferation and cytokine production.

Recommended dose of IMFINZI is 10 mg/kg administered as an IV solution over 60 minutes every two weeks. IMFINZI is available in two dosage forms and strengths: 500 mg/10mL (50 mg/mL) solution in a single-dose vial, and 120 mg/2.4mL (50 mg/mL) solution in a single-dose vial.

The applicant comments that a new code is warranted because IMFINZI is a unique molecule and there is no current HCPCS code to adequately describe the product.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish JXXXX, "Injection, durvalumab, 10 mg." Effective 1/1/19.

**SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

There was no primary speaker for this item. Written comments were received from the applicant in support of CMS' preliminary recommendation urging CMS to finalize this preliminary recommendation.

## **FINAL DECISION**

Establish J9173, “Injection, durvalumab, 10 mg.” Effective 1/1/19.

**Monday, May 14, 2018**

**Agenda Item # 14**

**Application# 18.012**

**TOPIC**

Request to establish a new Level II HCPCS code to identify triptorelin injection for extended-release, Trade Name: Triptodur

Applicant's suggested language: "JXXXX, Injection, triptorelin extended-release (Triptodur) 22.5mg. "

**BACKGROUND**

Arbor Pharmaceuticals, LLC submitted a request to establish a new Level II HCPCS code to identify Triptodur. Triptodur is a gonadotropin-releasing hormone (GnRH) agonist indicated for the treatment of pediatric patients 2 years and older with central precocious puberty (CPP). CPP is a condition where puberty starts too soon. With chronic and continuous administration of Triptodur, by 4 weeks after initiation of therapy, a sustained decrease in circulating levels of LH and FSH secretion and marked reduction in sex steroids are observed. The goal of this therapy is to suppress the gonadal steroid secretion through medical treatment or removal of the underlying cause and allow for normal sexual maturation and to reduce any potential psychosocial problems that may be related to early puberty.

Triptodur must be administered under the supervision of a physician. Dosage is a single intramuscular injection of 22.5 mg once every 24 weeks. LH levels should be monitored by initiation of, and during therapy. Triptodur is provided as a 22.5 mg triptorelin powder cake for reconstitution copackaged with a syringe containing 2 mL Sterile Water for Injection.

The applicant comments that a new code is warranted because to ensure physicians do not confuse this product with other products described by existing code J3315 "Injection, triptorelin pamoate, 3.75 mg" which is approved for the palliative treatment of adult men with prostate cancer.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish JXXXX, "Injection, triptorelin, extended-release, 3.75 mg." Effective 1/1/19.

**SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING**

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

**FINAL DECISION**

Establish J3316, “Injection, triptorelin, extended-release, 3.75 mg.” Effective 1/1/19.