

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

Wednesday, May 16, 2018

This HCPCS Code Application Summary document includes a summary of each HCPCS code application discussed at the May 16, 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.

Wednesday, May 16, 2018

Agenda Item # 1

Application# 18.010

TOPIC

Original request to establish a new Level II HCPCS code to identify axicabtagene ciloleucel for intravenous infusion, Trade Name: YESCARTA, subsequently amended to specify a dose descriptor to identify only treated cells resulting from “pre-treatment services.”

Current language Q2041: “Injection, “Axicabtagene ciloleucel, up to 200 million autologous Anti-CD 19 CAR T cells, including leukapheresis and dose preparation procedures, per infusion”, effective 4/1/18, as newly established following initial request.

Applicant’s suggested amended language, Q2041: “Axicabtagene ciloleucel, up to 200 million autologous anti-CD 19 CAR T cells, per infusion.”

BACKGROUND

Kite Pharma, Inc., a Gilead Company, submitted an initial request to establish a code and amended the request to revise newly established Level II HCPCS code to identify YESCARTA.

According to the applicant, YESCARTA is a CD 19 directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systematic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma (PMBCL), high grad B-cell lymphoma, and DLBCL arising from follicular lymphoma. YESCARTA addresses the unmet treatment need for patients who otherwise have no curative options, no standard therapy, and a short expected survival.

To prepare YESCARTA, a patient's own T cells are harvested and genetically modified ex vivo by retroviral transduction to express a chimeric antigen receptor (CAR) comprising an anti-CD 19 single chain variable fragment (scFv) linked to CD28 and CD3-zeta co-stimulatory domains. The anti-CD19 CAR T cells are expanded and infused back into the patient, where they can recognize and eliminate CD19-expressing target cells.

Dosing of YESCARTA is based on the number of chimeric antigen receptor (CAR)-positive viable T cells. The target dose is 2×10^6 CAR-positive viable T cells per kg of body weight or maximum of 2×10^8 CAR-positive viable T cells in approximately 68mL suspension. YESCARTA is supplied in a single-dose infusion bag containing approximately 68mL of frozen suspension of genetically modified autologous T cells. The entire contents of each single-use, patient specific bag is infused by gravity or a peristaltic pump within 30 minutes. Before YESCARTA is infused, patients are administered a lymphodepleting regimen of cyclophosphamide and fludarabine. Patients are also premedicated with acetaminophen and an

H1 antihistamine. FDA prescribing information includes a boxed warning regarding Cytokine Release Syndrome and Neurological Toxicities. YESCARTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).

The applicant comments that a unique code is warranted because YESCARTA is the only approved therapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systematic therapy, including DLBCL, PMBCL, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. In addition, Kite Pharma has requested that coding and payment for the resultant, treated cells for infusion be separate and apart from the leukapheresis and dose preparation procedures that creates them. This is "in order to ensure that billing and reimbursement confusion is eliminated, providers are relieved of significant administrative and financial systems re-work, and are adequately and separately reimbursed by YESCARTA pre-treatment services."

PRELIMINARY HCPCS CODING RECOMMENDATION

Newly established code Q2041 "Axicabtagene Ciloleucel, up to 200 Million Autologous Anti-CD19 CAR T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Infusion," effective 4/1/18, is available for assignment for insurers, if they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker respectfully requested a revision to the preliminary recommendation for Yescarta to incorporate only the therapy in the assigned code and remove "including leukapheresis and dose preparation procedures". The speaker also requested that CMS follow the norm for other Part B infused drugs and create a permanent J code be assigned to replace Q2041. In addition, the speaker indicated their support of the CMS recommendation to issue a G code for CAR T therapy pre-treatment services.

FINAL DECISION

Newly established code Q2041 has been revised to read as follows: "Axicabtagene Ciloleucel, up to 200 Million Autologous Anti-CD19 CAR positive viable T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Therapeutic Dose," The language revision is effective 1/1/19, and this code is available for assignment for insurers, if they deem appropriate.

Wednesday, May 16, 2018

Agenda Item # 2

Application# 18.001

TOPIC

Initial request to establish a new Level II HCPCS code to identify tisagenlecleucel, Trade name: KYMRIA, subsequently amended to specify a dose descriptor of “minimum of 200,000 T cells,” to accommodate anticipated FDA approval of a new (adult) indication.

Current language: Q2040 “Tisagenlecleucel, up to 250 million car-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion,” Effective 1/1/18, as newly established following initial request.

Applicant’s suggested amended language: “Tisagenlecleucel, minimum of 200,000 car-positive viable T cells, including leukapheresis and dose preparation procedures, per infusion,”

BACKGROUND

Novartis Pharmaceuticals submitted an initial request to establish a code and amended the request to revise newly established Level II HCPCS code Q2040 which currently reads "up to 250 million car-positive viable T cells" to instead read "minimum of 200,000 car-positive viable T cells." According to the applicant, KYMRIA is a CD-19 directed, genetically modified, autologous T cell immunotherapy. Autologous mononuclear T cells are collected through pheresis and cryopreserved. The cryopreserved cells are transported to Novartis' manufacturing facility, the cells are thawed and modified to express a chimeric antigen receptor (CAR) which is comprised of a murine single chain antibody fragment. The CAR identifies CD-19 fused to intracellular signals from 4-1BB and CD3 zeta. CD3 zeta is known to demonstrate antitumor activity and to initiate T cell activation. 4-1BB enhances the expansion and persistence of KYMRIA while vivo binding of the CAR targets and kills CD-19 tissue. The applicant claims that KYMRIA's first indication is for individuals who are 25 years of age or younger with refractory or relapsed B-cell precursor acute lymphoblastic leukemia (ALL). A second, anticipated indication, which has not yet been approved by the FDA, includes the treatment of diffuse large B cell lymphoma (DLBCL) who are ineligible for, or relapse after, an autologous stem cell transplant (ASCT). The product is administered as an autologous, patient-specific, one-time treatment. For treatment of acute lymphoblastic leukemia (ALL), KYMRIA is supplied as a sterile solution for IV infusion. The dosage is weight-based and includes up to 250 million CAR T cells. A single dose unit for the treatment of ALL contains 200,000 to 5 million CAR positive viable T cells per kg of patients' body weight of 50 kg or less. The dosage is 10 million to 250 million CAR positive viable T cells for patients weighing more than 50kg. For the second proposed indication of DLBCL, a single dose unit contains 60 million to 600 million CAR positive viable T cells. Before KYMRIA is infused, patients are premedicated with acetaminophen and an H1 antihistamine. FDA prescribing information includes a boxed warning regarding Cytokine Release Syndrome and Neurologic Toxicities. KYMRIA is available only

through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). The applicant comments that, although the current code descriptor could be used for DLBCL patients who require up to 250 million cells, the current dose descriptor cannot be used for the proposed new indication and patients who require up to 600 million cells. A code revision is warranted because the requested dose descriptor of a "minimum of 200 million" cells is consistent with the lower of the weight-based dosages for patients with ALL. The requested dose descriptor would also accommodate the proposed 600 million cell dose for the treatment of DLBCL.

PRELIMINARY HCPCS CODING RECOMMENDATION

Newly established code Q2040 "Tisagenlecleucel, up to 250 million car-positive T cells, including leukapheresis and dose preparation procedures, per infusion," effective 1/1/18, is available for assignment by insurers if they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker respectfully disagreed with CMS' preliminary recommendation and requests that the descriptor be modified to reflect dosing range for both of KYMRIAH's FDA approved indications. The speaker requested that CMS establish a new J code effective 1/1/19 with the requested Q2040 revised descriptor. In addition, the speaker requests that CMS maintains consistency in structure of HCPCS descriptors across CAR-T products.

FINAL DECISION

Discontinue Q2040 Tisagenlecleucel, up to 250 million car-positive T cells, including leukapheresis and dose preparation procedures, per infusion," Effective 1/1/19.

Establish Q2042 Tisagenlecleucel, up to 600 million car-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose," Effective 1/1/19.

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Agenda Item # 3

Application# 18.036

TOPIC

Request to establish a new Level II HCPCS code to identify bupivacaine liposome injectable suspension, Trade Name: EXPAREL

Applicant's suggested language: JXXXX: "Injection, bupivacaine liposome (Exparel), 1 mg".

BACKGROUND

Pacira Pharmaceuticals, Inc., submitted a request to establish a new Level II HCPCS code to identify EXPAREL. EXPAREL is a liposome injection of bupivacaine, an amide local anesthetic, indicated for single-dose infiltration into a surgical site to produce postsurgical analgesia.

According to the applicant, EXPAREL is unique among bupivacaine formulations in its demonstrated ability to reduce opioid use in patients being treated for postsurgical pain, offering a significant therapeutic advantage over other treatments. EXPAREL utilizes Pacira's unique DepoFoam platform to entrap bupivacaine in a multivesicular liposome system that permits extended release of the drug. Following initial injection, EXPAREL's amide anesthetic is slowly released from the product's DepoFoam liposome system, blocking the generation and conduction of nerve impulses, presumably by increasing the threshold for electrical excitation in the nerve, slowing the propagation of the nerve impulse, and reducing the rate of rise of the action potential.

The recommended dose of EXPAREL is based on the size of the surgical site and the volume required to cover the area. For example, for treatment of postsurgical pain following bunionectomy, 7 mL of EXPAREL is infiltrated into the tissues surrounding the osteotomy and 1 mL into the subcutaneous tissue. The maximum dosage should not exceed 266 mg (20mL). EXPAREL is injected slowly with a 25 gauge or larger bore needle into soft tissues with frequent aspiration. It is supplied in 20 mL single-use vials with 1.3% liposomal bupivacaine (13.3 mg/mL), packaged into cartons of 10.

The applicant comments that a new code is warranted because Exparel is a single-source drug.

PRELIMINARY HCPCS CODING RECOMMENDATION

CMS is delaying its preliminary code recommendation for EXPAREL pending further consideration of this matter.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker requested that CMS establish a new Level II code to describe EXPAREL under the ASP statute and for claims processing in the outpatient setting. The speaker indicated EXPAREL is a liposome injection of bupivacaine, and it is critical to enable identification of this single-source drug for the outpatient settings to be used as a long-acting analgesic.

FINAL DECISION

There is no Medicare payment policy need to establish a HCPCS "J" code to report infiltration of anesthesia infused into a surgical site. Existing code C9290 Injection bupivacaine liposome, 1 mg, can be assigned for use in the OPSS and ASC setting.

Wednesday, May 16, 2018

Agenda Item # 4

Application# 18.072

TOPIC

Request to revise the dose descriptor of existing HCPCS code A9587 which currently reads: "Gallium Ga-68, dotatate, diagnostic, 0.1 mCi"; to instead read: "A9587, Gallium Ga-68, dotatate, diagnostic, to per study dose, up to 5.4 mCi", to identify NETSPOT.

BACKGROUND

Advanced Accelerator Applications, USA, Inc., submitted a request to identify a kit for preparation of Gallium-68 dotatate injection, for intravenous use. Trade Name: NETSPOT. NETSPOT, after radiolabeling with Ga 68, is a radioactive diagnostic agent indicated for use with positron emission tomography (PET) for localization of somatostatin receptor positive neuroendocrine tumors (NET). Ga 68 dotatate has a high affinity for somatostatin subtype 2 receptors. It binds to cells that express somato-statin receptors indicating malignant cells. Gallium-68 is a B+ emitting radionuclide with a 68-minute half-life, and a high emission yield, properties favorable to PET imaging.

The recommended dose is 2 MBq/kg body weight (0.054 mCi/kg) up to 200 MBq (5.4 mCi). Although doses smaller than 5.4 mCi may be ordered, the price is the same per unit dose because one kit must be used per dose. NETSPOT is supplied as a single-dose kit for direct preparation of Gallium-Ga-68, dotatate, injection with dotatate and Gallium-68 chloride solution eluted from a Germanium-68/Gallium-68 generator (supplied separately) and with a reaction buffer.

"The per 0.1mCi descriptor creates variability in the reportable units" if measured based on radioactive decay; not all radiopharmaceuticals have a per mCi dose descriptor (some have a per dose descriptor), and "facilities have submitted 1 unit instead of units based on dose (e.g., 1 instead of 54 for 5.4 mCi) and expected reimbursement for the per study dose. This billing "error has led to payment delay and administrative burden."

The applicant comments that the current descriptor (0.1 mCi) requires providers to submit claims with up to 54 units while the product is purchased as a single unit regardless of the radioactivity. Additionally, the delivered dose can be +/- 10% of the prescribed dose, which could lead to errors on claims and unnecessary administrative burden. .

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to revise the descriptor of existing code A9587 has not been approved. The requested change does not improve the code. The existing descriptor of A9587, which reads, "Gallium ga-68, dotatate, diagnostic, 0.1 millicurie", 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 not to revise the descriptor of existing code A9587. The speaker requests a change to the descriptor from A9587, Gallium Ga-68 dotatate, diagnostic, 0.1 mCi to instead read "A9587, Gallium Ga-68, dotatate, diagnostic, per study dose". The speaker also indicated that the current descriptor has led to unnecessary administrative burden and errors in billing and payment, and confusion, and would align NETSPOT with other radiopharmaceuticals.

FINAL DECISION

This request to revise the descriptor of existing code A9587 has not been approved. The requested change does not improve the code. The existing descriptor of A9587, which reads, "Gallium ga-68, dotatate, diagnostic, 0.1 millicurie", is available for assignment by insurers if they deem appropriate.

Wednesday, May 16, 2018

Agenda Item # 5

Application# 18.081

TOPIC

Request to revise existing Level II HCPCS code A9588 which currently reads: "fluciclovine F 18, diagnostic 1 mCi," to instead read: "Fluciclovine F-18, diagnostic, per study dose". Trade Name: Axumin.

BACKGROUND

Blue Earth Diagnostics submitted a request to revise the dose descriptor of existing code A9588 from "1 mCi" to "per study dose."

According to the applicant, Axumin is a radioactive diagnostic agent for PET imaging for men with suspected prostate cancer reoccurrence, based on elevated blood levels of PSA following initial therapy. According to the applicant, fluciclovine F 18 is transported across mammalian cell membranes by amino acid transporters, which are known to be unregulated in prostate cancer cells. Axumin PET imaging of men with reoccurrence may identify sites of reoccurrence. Axumin has a physical half-life of 109.7 minutes. It is supplied in a 30mL multiple-dose vial containing 335-8200 MBq/mL (9-221 mCi/mL) fluciclovine F18 at calibration time and date. The recommended dose is 370MBq (10mCi) administered as an IV bolus injection.

The applicant comments that the current code descriptor does not adequately describe the product because Axumin is never prescribed in 1mCi increments. Rather, it is always provided as a 10mCi patient-ready dose at the time of calibration, which is the intended time of administration. Due to radioactive decay, and administration relative to time of calibration, a patient might receive more or less mCi; and the applicant states that "it is unclear to the providers how many units to bill" and "this confusion is leading to inconsistent billing;" and "a descriptor of "per study dose" would reduce confusion surrounding billing of activity of more or less than 10mCi."

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A9588, "Fluciclovine F18, diagnostic, 1 millicurie", is available for assignment by insurers if they deem appropriate.

This request to revise the description to existing code A9588 has not been approved as it does not improve the code.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation and requested that CMS reconsider the code descriptor read "per study dose".

The speaker indicated that the "per study dose" would improve the code, be consistent with other diagnostic PET radiopharmaceuticals, improve claims accuracy and reduce confusion among providers.

FINAL DECISION

No change. Use existing A9588 "Fluciclovine f-18, diagnostic, 1 millicurie"

Wednesday, May 16, 2018

Agenda Item # 6

Application# 18.054

TOPIC

Request to establish a new Level II HCPCS code to identify Bortezomib, Trade Name: Bortezomib for Injection.

Applicant's suggested language: Jxxxx-"Bortezomib for Injection, intravenous only, 3.5 mg per vial"

BACKGROUND

Fresenius Kabi USA, LLC, submitted a request to establish a new Level II HCPCS code to identify Bortezomib for Injection. According to the applicant, it is a targeted chemotherapy agent that functions as a proteasome inhibitor for treatment of adults with multiple myeloma and for treatment of adults with mantle cell lymphoma who have received at least 1 prior therapy.

Bortezomib for Injection is a reversible inhibitor of the chymotrypsin-like activity of the 26S proteasome in mammalian cells.

Bortezomib for Injection causes a delay in tumor growth in vivo in nonclinical tumor models, including multiple myeloma. The recommended starting dose of Bortezomib for Injection is 1.3mg/m², administered as a 3-5 second bolus intravenous injection. A lower starting dose is indicated for persons with hepatic impairment. Bortezomib for Injection is supplied in a single-dose vial that contains 3.5 mg of bortezomib as a lyophilized powder for reconstitution.

The applicant comments that a unique code is warranted because existing code categories are adequate to describe Bortezomib for injection because the product is a single-source drug with a single route of administration.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, Injection, bortezomib, not otherwise specified, 0.1 mg. Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker agrees with CMS' preliminary recommendation to establish a code but requested that "not otherwise specified" be removed to distinguish it from other market entries and suggested new language for the J code. In addition, the speaker requests that CMS establish a Q code before the J code effective 6/1/18.

FINAL DECISION

Establish J9044, Injection, bortezomib, not otherwise specified, 0.1 mg. Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 7

Application# 18.071

TOPIC

Request to revise existing Level II HCPCS code J9041, which currently reads: "Injection, bortezomib, 0.1mg", to include the brand name VELCADE in the descriptor.

Applicant's suggested language: "Injection, bortezomib (VELCADE), 0.1 mg."

BACKGROUND

Takeda Pharmaceuticals International submitted a request to revise existing Level II HCPCS code J9041 to include the brand name VELCADE in the descriptor. VELCADE is a proteasome inhibitor indicated for the treatment of patients with multiple myeloma and for the treatment of patients with mantle cell lymphoma.

The applicant comments that bortezomib is a reversible inhibitor of the chymotrypsin-like activity of the 26S proteasome in mammalian cells. Inhibition of the 26S proteasome prevents targeted proteolysis, which can affect multiple signaling cascades within the cell. Experiments have demonstrated that bortezomib is cytotoxic to a variety of cancer cell types in vitro. Additionally, bortezomib causes a delay in tumor growth in vivo in nonclinical tumor models, including multiple myeloma.

VELCADE can be administered by intravenous or subcutaneous injection. Each route of administration has a different reconstituted concentration. The recommended starting dose of VELCADE is 1.3 mg/m² administered either as a 3 to 5 second bolus intravenous injection or subcutaneous injection. Retreatment for multiple myeloma may start at the last tolerated dose. A lower starting dose may be used for patients with moderate or severe hepatic impairment.

VELCADE is supplied as individual cartons of 10mL vials containing 3.5 mg of bortezomib as powder for reconstruction and withdrawal of the appropriate individual patient dose powder.

The applicant comments that the requested revision to existing Level II HCPCS code J9041 to include the brand name Velcade in the descriptor is "necessary in order to ensure that this code is used only for the reporting and payment rate of Velcade." VELCADE is a single-source drug.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code J9041 which currently reads: "Injection, bortezomib, 0.1 mg", to instead read: "Injection, bortezomib (VELCADE), 0.1 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 in support of the preliminary recommendation and urged CMS to finalize this decision to include the brand name of the product in parenthesis in the descriptor language for this code.

FINAL DECISION

Revise existing code J9041 which currently reads: "Injection, bortezomib, 0.1 mg", to instead read: "Injection, bortezomib (VELCADE), 0.1 mg" Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 8

Application# 18.007

TOPIC

Request to establish a new Level II HCPCS code to identify a Human Amniotic Membrane, Trade Name: surgiGRAFT.

Applicant's suggested language: Q41XX- "surgiGRAFT amniotic membrane allograft, per square centimeter."

BACKGROUND

Synergy Biologics, LLC, submitted a request to establish a new Level II HCPCS code to identify surgiGRAFT. According to the applicant, surgiGraft is a minimally manipulated human amnion-only regenerative extracellular tissue matrix. It is derived from human placental tissue comprised of a single layer of cuboidal epithelial cells attached to several biologic reservoir layers including basement, compact, spongy, and fibroblast layers specifically processed to repair lost or damaged tissue. The processed allograft contains collagen types IV, V, and VII that will promote cellular differentiation and prevent adhesion formation.

SurgiGRAFT is intended for use in the following conditions: neuropathic ulcers, venous stasis ulcers, post-traumatic wounds, pre- and post- surgical wounds and pressure ulcers, diabetic wounds, burn wounds, scar tissue, scarring, and adhesion barrier up to and including nerve bundle and peripheral wrap as a wound covering. SurgiGRAFT is administered by placing the stromal side onto the external wound area followed by the clinician's standard closing procedures. If the desired wound closure is insufficient, then a second graft application would be conducted at the clinician's discretion.

According to the applicant, "the surgiGRAFT suite of products are amniotic tissue derived allografts administered by a physician and intended for reconstruction, repair, or replacement of a donor recipient's tissue." The package insert refers to surgical implantation. Information provided by applicant regarding physician office use is inconsistent and contradictory. According to the applicant, a code is needed to identify surgiGRAFT because "all physicians, hospital, and outpatient surgery centers will not entertain the use of surgiGRAFT without a dedicated HCPCS Level II code even though surgiGRAFT is the same as many other products on the market."

PRELIMINARY HCPCS CODING RECOMMENDATION

This request to establish a new code has not been approved as this application is not suitable for Level II HCPCS based on expected and reported setting of use.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation and urged CMS to reconsider their decision and establish a new Level II HCPCS code for SurgiGRAFT, an amniotic membrane allograft.

FINAL DECISION

Q4183 Surgigraft, per square centimeter. Effective 1/1/19

Wednesday, May 16, 2018

Agenda Item # 9

Application# 18.083

TOPIC

Request to establish a new Level II HCPCS code to identify REBINYN, Coagulation Factor IX, (Recombinant) GlycoPEGylated, Trade Name: REBINYN

Applicant's suggested language: JXXXX-"Injection, Factor IX (REBINYN Coagulation Factor IX, Recombinant) GlycoPEGylated), per IU."

BACKGROUND

Novo Nordisk, Inc., submitted a request to establish a new Level II HCPCS code to identify REBINYN. According to the applicant, REBINYN Coagulation Factor IX, Recombinant GlycoPEGylated is a purified recombinant factor IX (rFIX) with 40 kilodalton (kDa) polyethylene-gycol (PEG) conjugated to the protein to prolong its blood circulation and extend its half-life. It is indicated for use in adults and children with hemophilia B for on-demand treatment of bleeding and management of perioperative bleeding. The applicant also states that factor IX replacement in general is used to treat bleeding episodes, to manage bleeding during surgery, and to replace the missing factor to avoid further bleeding (prophylaxis).

The recommended dose for treatment of bleeding: minor/moderate bleeds-40 IU/kg, major bleeds-80 IU/kg (additional doses of 40 IU/kg can be given). The recommended dose for perioperative management: pre-operative dose 40 IU/kg (minor surgery) or 80 IU/kg (major surgery) repeated doses of 40 IU/kg (in 1-3 day intervals) within the first week and then once-weekly after major surgery may be administered until healing is achieved. It is administered by intravenous infusion after reconstitution only.

REBINYN is supplied as lyophilized powder in single-use vials containing nominally 500, 1000, or 2000 IU per vial. Each label for REBINYN states actual Factor IX potency in IU. The reconstituted solution contains approximately 125, 250, or 500 IU per mL of REBINYN.

The applicant comments that a new code is warranted because REBINYN is a unique, single source biologic, and recombinant clotting factor analog that is not described by existing codes. The applicant also comments that a new code would facilitate separate and appropriate payment while ensuring patient access.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish JXXXX, "Injection factor IX, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 IU." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS for holding a public meeting and indicated agreement and support with the preliminary coding recommendation for Rebinyn as this product plays an important role for blood clotting patients with severe and life threatening bleeding disorders. The speaker also indicates that Rebinyn provides a fixed dose administration compared to other products where dose calculation is required.

FINAL DECISION

Establish J7203, “Injection factor IX, (antihemophilic factor), recombinant), glycopegylated, (rebinyn), 1 IU.” Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 10

Application# 18.018

TOPIC

Request to establish a new Level II HCPCS code to identify bevacizumab-awwb, Trade Name: MVASI

Applicant's suggested language: JXXXX, Injection, bevacizumab-awwb, per 10 mg

BACKGROUND

Amgen submitted a request to establish a new Level II HCPCS code for bevacizumab-awwb, MVASI. MVASI is a recombinant humanized monoclonal IgG1 antibody that binds to and inhibits the biologic activity of human vascular endothelial growth factor (VEGF) in in vitro and in vivo assay systems. MVASI is indicated for the treatment of the following conditions with the recommended dosages:

- Non-squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy-15mg/kg IV every 3 weeks with carboplatin and paclitaxel •

Metastatic colorectal cancer in combination with chemotherapy-5 mg/kg IV every 2 weeks with bolus-IFL; 10 mg/kg IV every 2 weeks with FOLFOX4; or 5 mg/kg IV every 2 weeks or 7.5 mg/kg IV every 3 weeks with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin based chemotherapy after progression on a first- line bevacizumab product containing regime.

- Glioblastoma-10 mg/kg IV every 2 weeks •

Metastatic renal cell carcinoma in combination with interferon alfa-10 mg/kg IV every 2 weeks •

Persistent, recurrent or metastatic carcinoma of the cervix in combination with chemotherapy-15 mg/kg IV every 3 weeks

MVASI is supplied as a sterile solution containing 25 mg/ml bevacizumab-awwb in a single – dose vial. Single-dose vials contain: • 100mg of bevacizumab-awwb in 4 ml (25mg/ml) • 400mg of bevacizumab-awwb in 16 ml (25mg/ml)

According to the applicant no existing specific HCPCS code currently describes MVASI.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q510X "Injection, bevacizumab, 1 mg" Effective 1/1/19

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker requested that CMS revise the coding descriptor to add (MVASI) because it is an active ingredient. The speaker indicated that the coding descriptor should read "Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg.

FINAL DECISION

Establish Q5107 "Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg". Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 11

Application# 18.013

TOPIC

Request to establish a new Level II HCPCS code to identify its amnion allograft product, Trade Name: Cellesta Amniotic Membrane.

Applicant's suggested language: "XXXXX-Cellesta Amniotic Membrane, per square centimeter."

BACKGROUND

Ventris Medical, LLC., submitted a request to establish a new Level II HCPCS code to identify Cellesta Amniotic Membrane. According to the applicant, Cellesta Amniotic Membrane is a minimally manipulated amniotic membrane allograft intended for homologous use, and functions as a covering or barrier that offers protection from the surrounding environment in reparative and reconstructive procedures. These procedures include but are not limited to chronic wound repair, urologic and gynecological surgeries, and burn wound reconstruction.

The product is offered in both dry and hydrated formats, Cellesta provides a natural tissue matrix that retains a variety of innate biologic elements that support critical functions of the wound healing cascade. It also provides a protective barrier to tissue regeneration and can serve as an adhesion barrier to preserve natural gliding capabilities between adjacent tissues.

Cellesta Amniotic Membrane is a single layer allograft affixed to a layer of poly mesh. This can be sutured, or glued, or laid over the desired tissue. Once the poly mesh is removed, either side of the graft may be applied to the target tissue, as these grafts are provided orientation neutral.

Cellesta Amniotic Membrane is primarily and customarily used as a biological covering or scaffold in order to offer protection and enclose a healing environment in many repair and reconstructive procedures, particularly for the healing of chronic wounds. "Because it is for homologous use only, its basic functions are the same in the recipient as they are in utero-to serve as a selective barrier for the movement of nutrients, to protect from the surrounding environment, and to serve as a covering to enclose and retain fluid."

The amount of product used depends on the size of the wound, injury, and/or the scope of the surgery. Cellesta Amniotic Membrane is available wet or dry in 5 sizes: 2x2 cm, 2x4 cm, 2x6 cm, 4x4 cm, 4x6 cm, and 4x8 cm.

The applicant comments that a new code is warranted because all of the existing codes are brand specific and so it may be re

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "Cellesta, per square centimeter." 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 Q4184, "Cellesta, per square centimeter." Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 11

Application# 18.023

TOPIC

Request to establish a new Level II HCPCS code to identify an amniotic membrane, Trade Name: Cellesta Flowable Amnion.

Applicant's suggested language: "XXXXX-Cellesta Flowable Amnion, per 0.5 cc."

BACKGROUND

Ventris Medical LLC submitted a request to establish a new Level II HCPCS code to identify Cellesta Flowable Amnion. According to the applicant, Cellesta Flowable Amnion is a minimally manipulated amniotic membrane allograft regulated under Section 361 of the PHS Act. Cellesta Flowable Amnion is a chorion-free, human amniotic membrane intended for use as a regenerative wound filler for the treatment of acute, chronic and surgically-created wounds. Amniotic membrane is a natural tissue matrix that retains a variety of innate biologic elements that support critical functions of the wound healing cascade. Cellesta Flowable Amnion is a particulate form of amniotic membrane suspended in a saline solution for direct application, intended for homologous use only. Its inherent structural makeup allows it to act also as a cushion in dynamic environments. Its flowable format is specifically designed for treatment of deep dermal wounds, irregularly-shaped crevassing and tunneling wounds, augmentation of deficient/inadequate soft tissue, and other complex wound cases where a patch form of amniotic membrane may not provide complete wound coverage.

The prescribed dosage depends on size of the wound, injury, and/or scope of the surgery. Cellesta Flowable Amnion is available in 3 different volumes-0.5 cc, 1.0 cc, and 3.0 cc, in a pre-filled syringe. Cellesta Flowable Amnion is supplied by the donation of assenting, pre-screened women at the time of an elective, live, Caesarian birth.

The applicant comments that a new code is warranted because existing codes do not adequately describe Cellesta Flowable Amnion because they are all brand specific and none of them describe amnion-only pre-suspended in saline. In addition, the applicant comments that a new code is warranted for Cellesta Flowable Amnion so that it can be readily identifiable for third party claims processing and tracking.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX "Cellesta flowable amnion (25 mg per cc); per 0.5 cc." 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 Q4185 Cellesta flowable amnion (25mg per cc); per 0.5CC. Effective 1/1/19

Wednesday, May 16, 2018

Agenda Item # 12

Application# 18.085

TOPIC

Request to establish a new Level II HCPCS code to identify a bovine collagen wound covering, Trade Name: Connex.

Applicant's suggested language: Q4100-"Connex, per 0.5 gram."

BACKGROUND

Ventris Medical, Inc., submitted a request to establish a new Level II HCPCS code to identify the Bovine Type I Collagen wound covering Connex. According to the applicant, the function of the product is the management of wounds, absorbing wound fluid and maintaining a moist wound environment when applied to a wound surface. In addition, the applicant notes this product is not simply a wound filler but is an absorbent powder. It can be used in the management of partial and full thickness wounds, pressure and venous ulcers, venous stasis and diabetic ulcers, first and second-degree burns, cuts, abrasions and surgical wounds. The applicant indicates particular use in surgically-created, deep, or tunneling wounds. Connex comes as a sterile powder preloaded in a syringe for accurate and precise application to tunneling and irregularly-shaped wounds.

The applicant comments that a new code is warranted because existing codes are inadequate and other existing wound covering codes are brand specific.

PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A6010, "Collagen-based wound filler, dry form, sterile, per gram of collagen" is available for assignment by insurers, if they deem appropriate.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

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

FINAL DECISION

Existing code A6010, "Collagen-based wound filler, dry form, sterile, per gram of collagen" is available for assignment by insurers, if they deem appropriate.

Wednesday, May 16, 2018

Agenda Item # 13

Application# 18.025

TOPIC

Request to create a coding distinction between EpiFix and EpiCord by removing the brand name “EpiCord” from the descriptor of existing Level II HCPCS code Q4131 (which describes both EpiFix and EpiCord), and establishing a new code to specifically identify EpiCord.

Applicant’s suggested language: 1) Revise existing code Q4131 which currently reads “EpiFix or EpiCord per square centimeter”; to instead read “EpiFix, per square centimeter”; and 2) Establish Q41XX – “EpiCord, per square centimeter”

BACKGROUND

MiMedx, Inc. submitted a request to create a coding distinction between EpiFix and EpiCord. According to the applicant, EpiCord is a biologic made from human lyophilized umbilical cord that allows for application over exposed bone, tendon, nerve, muscle, joint capsule, and hardware.

EpiCord is minimally manipulated, dehydrated, non-viable cellular human umbilical cord allograft intended to provide an extracellular matrix (ECM) as a scaffold in the form of fibrillar collagens, fibronectin, laminins, and proteoglycans. The applicant comments that due to its unique thicker and stiffer structure, clinicians are able to apply or suture EpiCord to deep tunneling wounds where other products cannot fill the entire wound. The product is prescribed, obtained, and applied by a physician or other certified health professional in a variety of clinical settings, including hospital outpatient departments, ambulatory surgical centers and physician offices. A typical example would be treatment of a difficult to heal chronic diabetic foot ulcer that requires debridement.

The amount of product required is based on the size of the wound. EpiCord is provided in 2cm x 3cm and 3cm x 5cm sizes, which are cut to fit the wound. The applicant comments that a new code is warranted because EpiCord is a different and unique product from EpiFix, and that a new code would facilitate payer identification of the exact product used to benefit all payers. The applicant states that "medical coverage is different for each product and payers cannot distinguish what product was used based on claims adjudication. Many payers require additional information to distinguish which product was applied since there are different coverage criteria for each product."

PRELIMINARY HCPCS CODING RECOMMENDATION

1. Discontinue Q4131 "Epifix or Epicord, per square centimeter", effective 1/1/19.

2. Establish QXXXX Epifix, per square centimeter. Effective 1/1/19.

The request to establish a new Level II code for EpiCord has not been approved. Based on reported use, it is not suitable for inclusion in Level II HCPCS.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagreed with CMS' preliminary recommendation to add EpiCord to existing code Q4131 for EpiFix and requests that CMS establish a new codesince utilization has increased demonstrating a need for a separate unique product.

FINAL DECISION

1. Discontinue Q4131. Effective 1/1/19.
2. Establish Q4186 Epifix, per square centimeter. Effective 1/1/19.
3. Establish Q4187 Epicord, per square centimeter. Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 14

Application# 18.026

TOPIC

Request to establish a new Level II HCPCS code to identify a amniotic human tissue allograft, Trade Name: AmnioArmor.

Applicant's suggested language: "QXXXX- AmnioArmor, per sq centimeter".

BACKGROUND

Bone Bank Allografts, a subsidiary of Globus Medical, Inc., submitted a request to establish a new Level II HCPCS code to identify AmnioArmor. According to the applicant, AmnioArmor is a dehydrated human amniotic membrane allograft derived from the submucosa of placental tissue. It is intended for topical application as a wound covering for acute and chronic wounds. It contains dual collagen layers including a basement membrane and a stromal matrix that facilitate tissue regeneration and formation of granulation tissue. It contains growth factors including epidermal growth factor, (EGF) basic fibroblast growth factor (BFGF), keratinocyte growth factor (KGF), vascular endothelial growth factor (VEGF), transforming growth factors (TGFs), nerve growth factor (NGF), and many chemokines/cytokines, which have been demonstrated to be important for the treatment of wounds.

Once applied to the surgical site, AmnioArmor hydrates rapidly and can be hydrated with sterile saline or other sterile solution, if needed. Suture material or tissue adhesives may be used to apply the graft to the surgical site. AmnioArmor is available in several sizes for optimal coverage and placement, including 1 cm x 1 cm, 2 cm x 2 cm, 2 cm x 3 cm, 4 cm x 4 cm, 4 cm x 6 cm, 4 cm x 8 cm, and 16 mm dia.

The product is similar to EpiCord/EpiFix by MiMedx. The applicant is not making a claim of therapeutic distinction to similar products.

The applicant comments that a new code is warranted because there are no specific codes that accurately describe AmnioArmor. A dedicated code is needed to identify this product and differentiate it from other skin substitute products

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "AmnioArmor, per square centimeter." 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 Q4188 AminioArmor, per square centimeter. Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 15

Application# 18.060

TOPIC

Request to establish a new Level II HCPCS code to identify a dehydrated, micronized chorioamniotic membrane powder, Trade name: Artacent AC Powder.

Applicant's suggested language: Q4XXX- "Artacent AC Powder, per mg."

BACKGROUND

Tides Medical submitted a request for the creation of a new HCPCS code for Artacent AC Powder amnion/chorion membrane graft used for acute and chronic wound applications, including diabetic ulcers, pressure ulcers, venous stasis ulcers, burns and additional wounds that are refractory to more conservative care. These patients commonly present with multiple comorbidities and are often at a higher risk for amputations.

Artacent AC Powder is a dehydrated, micronized chorioamniotic membrane particulate processed from human chorioamniotic membrane, submucosa of voluntarily donated human placenta. The product contains essential growth factors shown to promote wound healing. Once applied, it integrates with the surrounding native tissues to stimulate wound healing.

Artacent AC Powder is supplied as a human amnion/ chorion powder for external application in one patient on a single occasion. Artacent AC Powder is applied directly onto the wound bed. The dosage for this product is per milligram and is supplied in the following allograft sizes: 20mg, 25mg, 40mg, 50mg, 100mg, 125mg, 140mg and 200mg.

The applicant comments that existing codes do not appropriately define Artacent AC Powder.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "Artacent AC, 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 Q4189, "Artacent AC, 1 mg." Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 15

Application# 18.061

TOPIC

Request to establish a new Level II HCPCS code to identify a human amnion/chorion membrane graft, Trade Name: Artacent AC.

Applicant's suggested language: Q4XXX- "Artacent AC, per sq cm."

BACKGROUND

Tides Medical Inc., submitted a request to establish a new Level II HCPCS code to identify Artacent AC. According to the applicant, Artacent AC is a human amnion/chorion membrane graft for use on acute and chronic wounds such as diabetic ulcers and venous stasis ulcers. It consists of a basement membrane and stromal matrix collagen layer.

The applicant comments that Artacent AC is a thin, collagenous membrane derived from the submucosa of donated human placenta. Its dual layer, bilateral application, and overall design facilitates improved handling, as well as easy manipulation and placement onto open wounds. According to the applicant, once the product is applied externally onto the wound bed, it integrates with the surrounding tissue and stimulates healing.

Artacent AC is sold in sizes: 1 x 1 cm, 2 x 2 cm, 3 x 3 cm, 3 x 4 cm, 4 x 4 cm, 4 x 6 cm, 4 x 8 cm, 6 x 6 cm, 9 mm disk, 12 mm disk, and 15 mm disk.

The applicant comments that a new code is warranted because no currently available HCPCS codes appropriately define Artacent AC.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code Q4169 to add "Artacent Wound or Artacent AC, per square centimeter." 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 Q4190 Artacent AC, per square centimeter. Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 16

Application# 18.062

TOPIC

Request to establish a new Level II HCPCS code to identify the human amnion patch, Trade Name: Restorigin Amnion Patch

Applicant's suggested language: QXXXX "Restorigin, per square centimeter."

BACKGROUND

Parametrics Medical on behalf of UMTB Biomedical, Inc., submitted a request to establish a new Level II HCPCS code to identify Restorigin Amnion Patch. According to the applicant, the product is derived from the amnion layer of fetal membranes in the umbilical cord. The allograft is comprised of amnion and chorion layers. The applicant claims that the product provides protection as well as a tissue matrix to reduce inflammation and scarring. The applicant comments that the Restorigin Amnion Patch is appropriate for individuals with chronic, non-healing wounds and burns.

The product is supplied in a variety of sizes per centimeter. It is contraindicated in individuals with sensitivities to Gentamicin, Vancomycin, and Bacitracin. The applicant claims that the product is "restricted to homologous use as a soft-tissue barrier or wound covering." The product must also be administered by a "licensed healthcare professional" in inpatient, outpatient, and ambulatory settings. The applicant comments that a new code is warranted because reporting of miscellaneous code Q4100, requires claims to be manually reviewed and there is the likelihood of claim denial and slower payment. And "providers must include additional documentation regarding Restorigin Amnion Patch and cross-walk charges to similar products which do have specific codes, when submitting claims for services."

The applicant also claims that the current code only includes "low cost skin substitutes," resulting in inaccurate cost data collection.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "Restorigin, per square centimeter." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS for review of their applications and expressed agreement with the preliminary recommendation.

FINAL DECISION

Establish Q4191, "Restorigin, per square centimeter." Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 16

Application# 18.064

TOPIC

Request to establish a new Level II HCPCS code to identify an injectable human amnion allograft, Trade Name: Restorigin AFT.

Applicants suggested language: QXXXX: "Restorigin AFT, injectable, .25cc" .

BACKGROUND

Parametrics Medical, submitted a request to establish a code to identify Restorigin AFT.

Restorigin AFT is intended for the treatment of non-healing wounds and burn injuries. Restorigin AFT is a versatile and manageable amniotic fluid product that is derived from donated human birth tissue and fluid. The dosage is calculated in cubic centimeters (cc), and is dependent upon the size of the wound or injury site. Restorigin AFT is not currently micronized or lyophilized and therefore there is no mg to cc conversion. Restorigin AFT is supplied in .25ml, .5ml, 1.0ml, and 2.0ml single use vials and is intended for external application.

The applicant comments that a new code is warranted because a product specific Q-code will allow for the efficient coding and billing of Restorigin AFT and permit the collection of cost data allowing for proper assignment of the product into the low or high cost category.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish Q41XX "Restorigin, 1 cc" Effective 1/1/19

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker expressed appreciation to the HCPCS Workgroup for reviewing the Parametrics Medical applications and agree with the preliminary recommendation.

FINAL DECISION

Establish Q4192 "Restorigin, 1 cc" Effective 1/1/19

Wednesday, May 16, 2018

Agenda Item # 17

Application# 18.063

TOPIC

Request to establish a new Level II HCPCS code to identify the human dermal allograft, Trade Name: Coll-e-Derm.

Applicant's suggested language: QXXXX "Coll-e-Derm, per square centimeter"

BACKGROUND

Parametrics Medical submitted a request to establish a new Level II HCPCS code to identify the Coll-e-Derm. According to the applicant, the Coll-e-Derm is a dermal allograft derived from human dermal tissue. The applicant claims that it is comprised of collagen, elastin and proteoglycans which allow cellular regeneration upon implantation. This regeneration supports wound and burn healing for wounds that have not healed with conventional treatment. The product is placed over a wound and may be sutured when necessary.

Use of the product is restricted to the "replacement of damaged, or inadequate homologous tissue" and the repair of soft tissue defects in those with "chronic, non-infected, full-or partial thickness diabetic or venous insufficiency ulcers." Use is also recommended for those with second or third degree burns. The product must be used by a licensed healthcare professional in inpatient, outpatient, and ambulatory settings. The applicant lists no contraindications.

The applicant comments that a new code is warranted because use of code Q4100, requires providers to "cross-walk" the charges of similar products with other Q codes. In addition, all Q4100 codes are classified as "low-cost" despite the price of the product. This results in inaccurate data collection.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX "Coll-e-Derm, per square centimeter." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker expressed appreciation for the HCPCS Workgroup reviewing the Parametrics Medical applications and agrees with the preliminary recommendation.

FINAL DECISION

Establish Q4193 "Coll-e-Derm, per square centimeter." Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 18

Application# 18.077

TOPIC

Request to establish a new Level II HCPCS code to identify a chorion membrane allograft, Trade Name: Novachor

Applicant's suggested language: Q41xx-"Novachor per square centimeter."

BACKGROUND

Organogenesis, Inc., submitted a request to establish a new Level II HCPCS code to identify Novachor. According to the applicant, Novachor is comprised of the chorion layer of the placental membranes. This membrane is known to contain 1) collagen types I, III, V, VI laminin, fibronectin and proteoglycans; 2) trophic proteins; 3) growth factors; 4) Tissue Inhibitors of Matrix Metallo-proteinases (TIMPs); and 5) pluri-potential cells. It is intended to be applied as a graft for acute and chronic wounds, including but not limited to, neuropathic ulcers, venous stasis ulcers, pressure ulcers, burns, post-traumatic wounds and post-surgical wounds. It is administered by applying the product to a wound using sutures or other fixation method. The product provides a physical covering which protects the wound and supports endogenous healing.

The amount of Novachor used depends on the size of the wound being treated. Novachor is packaged in the following size: 2.5 x 2.5 cm.

The applicant comments that a new code is warranted to appropriately identify and reimburse Novachor in the full range of care settings and to provide coding consistent with other clinically similar products.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "Novachor, per square centimeter." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

FINAL DECISION

Establish Q4194 Novachor, per square centimeter. Effective 1/1/19

Wednesday, May 16, 2018

Agenda Item # 19

Application# 18.078

TOPIC

Request to establish a new Level II HCPCS to identify PuraPly Antimicrobial XT Wound Matrix, Trade Name: Puraply AM XT

Applicant's suggested language: Q41XX-"PuraPly AM XT, per square centimeter".

BACKGROUND

Organogenesis, Inc., submitted a request to establish a new code to identify PuraPly Antimicrobial XT Wound Matrix, Puraply AM XT. According to the applicant, PuraPly Antimicrobial XT Matrix (Puraply AM XT) is a five layer fenestrated and cross-linked sheet of porcine collagen, coated with polyhexamethylene biguanide hydrochloride (PHMB) to resist microbial colonization and reduce microbial penetration within the matrix.

According to the applicant, Puraply AM XT is intended for the management of partial and full thickness wounds, surgical and trauma wounds, and certain types of ulcers. It is administered by applying the product to a wound using sutures or other method of fixation. The product is supplied in sheet forms of 5x5 cm or 6x9 cm.

The applicant comments that "there is no code that is specific to Puraply AM XT" and "a unique code is necessary to appropriately identify and reimburse PuraPly Antimicrobial XT Matrix Puraply AM XT in the full range of site of care settings and for consistency with other similar products."

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code Q4172 which currently reads "Puraply or puraply AM, per square centimeter" to instead read: "PuraPly, Puraply AM, or Puraply XT, per square centimeter." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

There was no primary speaker for this item.

FINAL DECISION

1. Discontinue Q4172 Puraply or puraply am, per square centimeter
2. Establish Q4195 Puraply, per square centimeter

3. Establish Q4196 Puraply am, per square centimeter

4. Establish Q4197 Puraply XT, per square centimeter

All effective 1/1/19

Wednesday, May 16, 2018

Agenda Item # 20

Application# 18.070

TOPIC

Request to establish a new Level II HCPCS code to identify an amniotic membrane allograft, Trade Name: Genesis Amniotic Membrane.

Applicant's suggested language: QXXXX-"Genesis Amniotic Membrane, per square centimeter."

BACKGROUND

Genesis Biologics, Inc., submitted a request to establish a new Level II HCPCS code to identify the Genesis Amniotic Membrane. According to the applicant, the Genesis Amniotic Membrane is a dehydrated, collagenous human tissue allograft used for the treatment of acute and chronic wounds, soft tissue injuries, and infection prevention. The placental product is said to contain collagen, cytokines, and growth factors that aid in wound healing and reduced scarring.

According to the applicant, the Genesis Amniotic Membrane is indicated for use for diabetic patients experiencing issues with wound healing. It is also indicated for patients who have undergone surgical reconstructions and other complex operative procedures. The allograft is derived from amniotic sac of donors post-caesarian section delivery. The product is applied in a manner that prevents displacement over the open wound. There is no need for any suturing or adhesions upon application. The Genesis Amniotic Membrane is also available in multiple sizes, ranging from 1x1cm² to 7x15cm².

The applicant comments that a new code is warranted because there are no existing HCPCS codes that adequately describe the Genesis Amniotic Membrane.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "Genesis amniotic membrane, per square centimeter." 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 Q4198, "Genesis amniotic membrane, per square centimeter." Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 21

Application# 18.066

TOPIC

Request to revise existing Level II HCPCS code Q4133 which currently reads: "Grafix PRIME and GrafixPL Prime, per square centimeter," to instead read: "Grafix Prime, GrafixPL PRIME, Stravix and StravixPL, per square centimeter."

BACKGROUND

Osiris Therapeutics, Inc. submitted a request to add Stravix and StravixPL to an existing Level II HCPCS code, Q4133, which currently describes Grafix PRIME and GrafixPL PRIME. According to the applicant, Stravix and Stravix PL are thicker versions of Grafix PRIME and GrafixPL PRIME. The products, which use umbilical amnion and Wharton's Jelly to support wound repair, are recommended for individuals with ulcers, burns, Pyoderma Gangrenosum, Epidermolysis Bulosa, and other types of wounds.

Physicians prescribe one of the two sizes of the products, either 2cm x 4cm or 3cm x 6cm, based on the size of the wound. Stravix is supplied using cryopreservation in a plastic jar. StravixPL is supplied between plastic mesh using lyopreservation. All of the products are intended for single use and applied directly to the wound.

The applicant comments that "Existing HCPCS code Q4133 should be utilized to describe Grafix PRIME, GrafixPL PRIME, Stravix, and StravixPL, as the four product configurations – aside from product thickness – have the same composition, an identical mechanism of action, closely similar characteristics and properties, the same dosage, the same route of administration and operation," and are "regulated by the same FDA".

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing Level II HCPCS code Q4133 which currently reads: Grafix PRIME and GrafixPL Prime, per square centimeter, to instead read: Q4133, Grafix Prime, Grafix PL PRIME, Stravix and StravixPL, per square centimeter. 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

Revise existing Level II HCPCS code Q4133 which currently reads: Grafix PRIME and GrafixPL Prime, per square centimeter, to instead read: Q4133, Grafix Prime, Grafix PL PRIME, Stravix and StravixPL, per square centimeter. Effective 1/1/19.

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Wednesday, May 16, 2018

Agenda Item # 22

Application# 18.069

TOPIC

Request to establish a new Level II HCPCS code to identify a chorion-free amniotic membrane derived allograft, Trade Name: XWRAP.

Applicant did not suggest language.

BACKGROUND

Applied Biologics, LLC submitted a request to identify the XWRAP which is manufactured by Crown Peak Industries, LLC. According to the applicant, the XWRAP is a chorion-free amniotic membrane derived allograft. It is indicated for "homologous use" as a barrier or protective covering for tissue repair and reconstruction sites. No suturing is required for application.

According to the applicant, the chorion layer is omitted in processing because it may contain traces of a specific blood type which bears the risk of rejection upon product use. The amniotic membrane used to manufacture the XWRAP is harvested from the donations of pre-screened mothers during Cesarean deliveries.

According to the applicant, the product is available in hydro (packaged in saline solution), dry, and dry without mesh. It is also available in multiple sizes. The applicant comments that a new code is warranted because there are no existing HCPCS codes that adequately describe the XWRAP.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "XWRAP, per square centimeter." 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 Q4204 XWRAP, per square centimeter. Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 23

Application# 18.067

TOPIC

Request to establish a new Level II HCPCS code to identify an autologous Homologous Skin tissue product, Trade Name: SkinTE

Applicant's suggested language: QXXXX-"SkinTE, per square centimeter."

BACKGROUND

PolarityTE, Inc., submitted a request to establish a new Level II HCPCS code to identify SkinTE. According to the applicant, SkinTE is a fully autologous, homologous skin product intended to be used for the repair, reconstruction, replacement, supplementation, or regeneration of defects or functional losses of the skin of human patients.

The applicant comments that SkinTE is manufactured from a harvested sample of the patient's full-thickness skin, composed of viable skin cells and an organized extracellular matrix, with no additional cell or tissue source from another human (allogeneic) or (xenogeneic). Following application to a wound bed, the product functions to regenerate full-thickness functional skin across the entire surface, including all layers (epidermis, dermis, hypodermis), and regenerate functional appendages native to skin. The product is intended to be used by physicians for homologous uses of the skin and integumentary system. The product is appropriate from treatment of acute burns requiring excision, grafting, and chronic wounds. Patients with functional loss of skin due to scarring may also be appropriate for treatment with SkinTE.

SkinTE is patient and case specific, intended for autologous use, and single application only. It is provided as a viscous tissue product with a syringe (or multiple syringes if appropriate). The dosage of SkinTE corresponds to the surface area of the wound being treated in square centimeters. Currently, the miscellaneous code Q4100, skin substitute not otherwise specified, is used for billing.

The applicant comments that a new code is warranted because wound products are product specific and do not appropriately describe the SkinTE and its ability to regenerate the patient's own skin.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "Skin TE, per square centimeter." 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 expressing agreement with the preliminary recommendation to establish a new Q code for Skin TE.

FINAL DECISION

Establish Q4200, "Skin TE, per square centimeter." Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 24

Application# 18.068

TOPIC

Request to establish a new Level II HCPCS code to identify a regenerative human placental allograft, Trade Name: Matrion

Applicant's suggested language: QXXXX-"Matrion, per square centimeter, decellularized dermal allograft."

BACKGROUND

LifeNet Health submitted a request to establish a new Level II HCPCS code to identify Matrion. According to the applicant, Matrion is a regenerative human placental allograft procured and processed from donated human tissue. Matrion is a matrix scaffold derived from an intact decellularized placental membrane comprising both amniotic and chorionic layers. The resulting decellularized placental membrane is available in membrane, injectable, and sponge configurations for use in wound, tendon, and nerve applications. Decellularized placental membrane modulates inflammation in the surgical site, enhances healing, and acts as a barrier. Matrion is supplied as a decellularized placental allograft and is freeze-dried and stored at ambient room temperature.

Matrion is supplied in 4x4 cm, 4x6 cm, 2x4 cm, 2x3 cm, and 2x2 cm sizes. It is applied topically for chronic wounds and can be sutured, Steri-stripped or stapled to the wound and edges. The amount of product used depends upon the size of the defect as well as the number of wounds being treated.

The applicant comments that a unique code is warranted because Matrion is processed utilizing a proprietary and patented technology

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX, "Matrion, per square centimeter." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS and expressed agreement with the preliminary recommendation.

FINAL DECISION

Establish Q4201, "Matrion, per square centimeter." Effective 1/1/19.

Wednesday, May 16, 2018

Agenda Item # 25

Application# 18.084

TOPIC

Request to revise the descriptor of existing code Q4137, which currently reads: “AMNIOEXCEL or biodexcel, per square centimeter,” to instead read: “AmnioExcel, AmnioExcel Plus, or BioDExCel, per square centimeter.”

BACKGROUND

Integra Life Sciences Sales, Inc. submitted a request to revise the descriptor of existing code Q4137 to add AMNIOEXCEL Plus. According to the applicant, AMNIOEXCEL Plus is a human placental allograft membrane intended for use as a topically applied wound covering. It is intended for homologous uses for the repair, reconstruction, and replacement of skin. The graft size is determined by the physician based on the wound size, applied topically, and anchored using the physician's choice of fixation.

AMNIOEXCEL Plus is supplied in multiple sizes and geometric configurations including: 17mm disk, 2 cm x 2 cm, 3 cm x 4 cm, 3 cm x 3 cm, 4 cm x 5 cm, and 5 cm x 8 cm. It is dehydrated during processing. AMNIOEXCEL Plus is an extension of the AMNIOEXCEL and BioDExCel product line that incorporates additional layers of human-sourced amnion and chorion to provide higher levels of cellular components and to aid the product's handling characteristics.

The applicant comments that an update to existing code Q4137 is necessary in order to add Amnioexcel Plus, as the descriptor was originally developed to include AMNIOEXCEL and BioDExCel only.

PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code Q4137 to read: AmnioExcel Plus or biodexcel, per square centimeter. 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 thanking the HCPCS workgroup for the preliminary recommendation, to revise the code descriptor for Q4137 to include AmnioExcel Plus, a new line extension to the AmnioExcel and BioDExCel product family. The applicant requested that the descriptor include all three product names in the final decision.

FINAL DECISION

Revise Q4137 "Amnioexcel or biodexcel, per square centimeter" to read "Amnioexcel, Amnioexcel Plus or biodexcel, per square centimeter"

Wednesday, May 16, 2018

Agenda Item # 26

Application# 18.082

TOPIC

Request to establish a new Level II HCPCS code to identify an allograft adipose matrix, Trade Name: Renuva.

Applicant's suggested language: Qxxxx-"Renuva Allograft Adipose Matrix, 0.5 cc."

BACKGROUND

The Musculoskeletal Transplant Foundation submitted a request to establish a new Level II HCPCS code to identify Renuva. According to the applicant, Renuva is an allograft scaffold derived from human donated adipose tissue. It is intended to be used as a scaffold for the replacement of damaged or inadequate integumental adipose tissue such as those in patients with facial lipodystrophy; for tissue augmentation to prevent diabetic foot ulceration recurrence; and other homologous uses. According to the applicant, Renuva Allograft Adipose Matrix, when injected, physiologically acts like autologous fat, resembling dermal tissue fillers and promoting vascular angiogenesis. This is essential for localized adipogenesis as the graft is incorporated and remodeled in the area of the damaged or inadequate adipose tissue.

The matrix is available in 3 sizes: 1.5cc tissue package, 3cc tissue package and 5cc tissue package.

The applicant comments that a new code is warranted for a brand specific HCPCS code for Renuva Allograft Adipose Matrix to appropriately and efficiently administer payment and coverage policies.

PRELIMINARY HCPCS CODING RECOMMENDATION

This request for a new code was not approved. Renuva is not FDA approved for the clinical indications specified in this application (eg. facial lipodystrophy).

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker disagrees with CMS' preliminary recommendation and requests reconsideration of this request. The preliminary recommendation indicated that Renuva is not FDA approved for the clinical indications specified in the application. The speaker respectfully requests that CMS establish QXXXX for Renuva. The speaker indicated that Renuva is for homologous use of the tissue form and does not require FDA approved clinical indication. The speaker also indicated that Renuva was developed as an alternative to surgical autologous fat

grafting, mitigating or eliminating the morbidity associated with the harvesting and grafting portions of this invasive procedure.

FINAL DECISION

This request for a new code for Renuva is not approved. Renuva is not FDA approved for the clinical indications specified in this application (e.g. facial lipodystrophy). For Medicare coding guidance and information regarding covered indications for dermal fillers for facial lipodystrophy, see national coverage determination (NCD) 250.5. For coding guidance, contact the insurers in whose jurisdictions a claim would be filed. For private sector health insurance systems, please contact the individual private insurance entity. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. For Medicare, contact the Medicare contractor.

Wednesday, May 16, 2018

Agenda Item # 27

Application# 18.086

TOPIC

Request to revise the descriptor of existing code Q4165 which currently reads: “Keramatrix, per square centimeter” to instead read: “Keramatrix, per square centimeter, or Keroxx Flowable Wound Matrix, injectable, 1 cc”

BACKGROUND

Molecular Biologicals, Inc. submitted a request to revise the descriptor of existing code Q4165 to add a flowable version of the Keroxx product. According to the applicant, Keroxx Flowable Wound Matrix is an advanced wound matrix comprised of keratin enriched proteins containing the active ingredient Replicine Functional Keratins which are biologically active proteins extracted using proprietary processes where the inherent alpha-helical structure of the keratin molecule remains intact. These keratin proteins are extracted from sheep wool and are placed in an open celled injectable gel format. The applicant comments that when Keroxx is injected in the wound bed, the Replicine Functional Keratins are absorbed into the developing tissues in the wound and provide a biocompatible matrix or scaffold for cellular proliferation, migration and capillary growth so as to aid in the growth of new tissue. The Replicine Functional Keratins have been shown to activate keratinocyte cells present in the wound and stimulate them to quickly enter a hyperproliferative phase essential for wound healing.

The applicant comments that the existing code Q4165 Keramatrix, per square centimeter does describe the technology, but that the formulation is different (Keramatrix is a sterile, single-use matrix sheet whereas Keroxx Flowable Wound Matrix is an injectable). Keroxx flowable is used to treat patients with chronic wounds such as pressure ulcers, diabetic ulcers, donor sites and grafts.

Keroxx flowable is supplied in single use kits containing one 6 cc syringe with Keroxx Flowable Wound Matrix and one flexible injector.

The applicant comments that a revision to the descriptor for the code is warranted because the existing code Q4165 describes the technology, but the formulation is different.

PRELIMINARY HCPCS CODING RECOMMENDATION

Establish QXXXX-"Keroxx (2.5g/cc), 1cc." Effective 1/1/19.

SUMMARY OF PRIMARY SPEAKER COMMENTS AT THE PUBLIC MEETING

The primary speaker thanked CMS and agreed with the preliminary recommendation to establish a Q code for Keroxx.

FINAL DECISION

Establish Q4202 "Keroxx (2.5g/cc), 1cc." Effective 1/1/19.