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


**Monday, May 13, 2019 9:00 am - 5:00 pm**


**CMS Auditorium**
**7500 Security Boulevard**
**Baltimore, Maryland 21244-1850**


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

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


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

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

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 1**

**Application 19.009**

Request to revise existing Level II HCPCS code Q4163 which currently reads "Woundex, bioskin, per square centimeter" to include AxoBioMembrane.

Applicant's suggested language: Q4163 "Amnion bio, WoundEX, AxoBioMembrane, per square centimeter."

**Application 19.041**

Request to revise existing Level II HCPCS code Q4163 by adding Axolotl Graft and Axolotl DualGraft

Applicant's suggested language: Q4163 "WoundEX, BioSkin, Axolotl Graft, Axolotl DualGraft, per square centimeter."

**Application 19.047**

Request to establish a single new Level II HCPCS code to identify human amniotic flowable allograft, intended for homologous use and to support the repair of soft tissue injury, Trade names: Axolotl Ambient and Axolotl Cryo.

Applicant's suggested language: QXXXX "Axolotl Ambient, Axolotl Cryo, per milliliter."

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 2**

**Application 19.099**

Request to establish a new Level II HCPCS code to identify a human umbilical tissue membrane allograft, Trade Name: SurgiCORD.

Applicant's suggested language: QXXXX "SurgiCORD per sq. cm."

**Application 19.100**

Request to establish a new Level II HCPCS code to identify a bilayer human amniotic tissue allograft, Trade Name: SurgiGRAFT-DUAL

Applicant's suggested language: QXXXX "SurgiGRAFT-DUAL per sq. cm."

**Agenda Item # 3**

**Application 19.030**

Request to establish a new Level II HCPCS code to identify Novafix, a dehydrated human amniotic membrane allograft indicated for use in the management of wounds. Trade name: Novafix[TM].

Applicant's suggested language: QXXXX "Novafix[TM], per sq. cm."

**Agenda Item # 4**

**Application 19.031**

Request to establish a new Level II HCPCS code to identify SurGraft, a "sheet-like" human amniotic membrane scaffold which "functions as a wound covering". Trade name: SurGraft®.

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

## CMS HCPCS Public Meeting

## Agenda Item # 5

**Application 19.101**

Request to establish a new Level II HCPCS code to identify an Amniotic/Chorionic Tissue Allograft, Trade Name: AmnioWrap2.

Applicant's suggested language: QXXXX "AmnioWrap2, per square cm."

## Agenda Item # 6

**Application 19.033**

Request to revise existing Level II HCPCS code Q4163 which currently reads "Woundex, bioskin, per square centimeter"; to include "Membrane Graft and Membrane Wrap" human amniotic allograft membranes. Trade names: Membrane Graft and Membrane Wrap.

Applicant's suggested language: Q4163 "Amnion bio, WoundEX, Membrane Graft and Membrane Wrap, per square centimeter."

**Application 19.034**

Request to establish a single new Level II HCPCS code to identify Human amniotic flowable allografts. Trade names: Fluid Flow and Fluid GF.

Applicant's suggested language: QXXXX "Fluid Flow and Fluid GF, per milliliter."

**Application 19.074**

Request to establish a new Level II HCPCS code to identify an autologous, homologous human skin product. Trade Name: MyOwn Skin™

Applicant's suggested language: QXXXX "MyOwn Skin™, per square centimeter."

**CMS HCPCS Public Meeting**

**Agenda Item # 7**

**Application 19.051**

Request to revise existing Level II HCPCS code Q4169 which identifies Artacent™ Wound to include single and dual layer products.

Applicant's suggested revised language: Q4169 "Artacent Wound, single or dual layer, per sq cm."

**Application 19.052**

Request to establish a new Level II HCPCS code to identify a "healing patch" comprised of Artacent Cord Human Umbilical Cord, Trade Name: Artacent Cord.

**Agenda Item # 8**

**Application 19.071**

Request to establish a new Level II HCPCS code to identify an umbilical cord allograft, Trade Name: Cellesta™ Cord.

Applicant's suggested language: QXXXX "Cellesta™ Cord, per square centimeter."

**Application 19.072**

Request to establish a new Level II HCPCS code to identify a dual layer human amniotic membrane allograft, Trade Name: Cellesta™ Duo.

Applicant's suggested language: QXXXX "Cellesta™ Duo, per square centimeter."

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 9**

**Application 19.061**

Request to establish a new Level II HCPCS code to identify a human amnion allograft, Trade Name: AlloGen Liquid.

Applicants suggested language: QXXXX "AlloGen injectable, per ml."

**Agenda Item # 10**

**Application 19.063**

Request to establish a new Level II HCPCS code to identify a "dehydrated cell and protein concentrate (dCPC) injectable derived from human amniotic fluid", Trade Name: Ascent[TM].

Applicant suggested language: Qxxxx "Ascent[TM], per milligram."

**Agenda Item # 11**

**Application 19.088**

Request to establish a single new Level II HCPCS code to identify WoundFix[TM] Membrane BioWound[TM] Membrane.

Applicant's suggested language: Q41XX "WoundFix[TM] Membrane & BioWound[TM] Membrane, per square centimeter."

**Application 19.089**

Request to establish a single new Level II HCPCS code to identify human, chorion-based membranes. Trade Names: WoundFix[TM] Plus Membrane and BioWound[TM] Plus Membrane

Applicant's suggested language: Q41XX "WoundFix[TM] Plus Membrane & BioWound[TM] Plus Membrane, per square centimeter."

## CMS HCPCS Public Meeting

**Application 19.090**

Request to establish a single new Level II HCPCS code to identify human placental tissue based membranes. Trade Names: WoundFix<sup>TM</sup> XPlus Membrane and BioWound<sup>TM</sup> XPlus Membrane.

Applicant's suggested language: Q41XX "WoundFix<sup>TM</sup> XPlus Membrane & BioWound<sup>TM</sup> XPlus Membrane, per square centimeter."

# Agenda Item # 12

**Application 19.036**

Request to establish a new Level II HCPCS code to identify a human acellular dehydrated dermis regenerative tissue matrix. Trade name: BellaCell HD.

Applicant's suggested language: "BellaCell HD Regenerative Tissue Matrix, per square centimeter."

**Application # 19.037**

Request to establish a new Level II HCPCS code to identify a human acellular dermal matrix. Trade name: SureDerm.

Applicant's suggested language: "SureDerm Acellular Dermal Matrix, per square centimeter."

# Agenda Item # 13

**Application 19.055**

Request to establish a new Level II HCPCS code to identify Human Keratin Matrix derived from human hair. Trade Name: ProgenaMatrix<sup>TM</sup>.

**CMS HCPCS Public Meeting**

## Agenda Item # 14

**Application 19.059**

Request to revise existing Level II HCPCS code Q4165 "Keramatrix, per square centimeter" to add an additional similar product, Kerasorb.

Applicant's suggested language: Q4165 "Keramatrix, per square centimeter or Kerasorb Wound Matrix, per square centimeter."

## Agenda Item # 15

**Application 19.095**

Request to revise existing Level II HCPCS code Q4122, which currently reads: "DermACELL, per square centimeter", to instead read: "DermACELL, DermACELL AWM, DermACELL AWM Porous, per square centimeter."

## Agenda Item # 16

**Application 19.070**

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, 0.5cc."

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**CMS HCPCS Public Meeting**

**Agenda Item # 17**

**Application 19.004**

Request to establish a single new Level II HCPCS code to identify a 100% native, freeze-dried, Type-I bovine Collagen matrix for use for wound management, Trade names: ACM Surgical Collagen and ACM Surgical Extra Advanced Collagen.

Applicant's suggested language: QXXXX "ACM Surgical Collagen/ACM Surgical Extra Advanced Collagen, per square centimeter."

**Application 19.113**

Request to establish a new Level II HCPCS code to describe a 100% native Type 1 bovine collagen powder for use in wound management, Trade Name: ACM Surgical Extra Advanced Collagen Powder.

Applicants suggested language: QXXXX "ACM Surgical Extra Advance Collagen Powder, per gm."

**Agenda Item # 18**

**Application 19.087**

Request to revise existing Level II HCPCS code Q4133 which currently reads: "Grafix prime, grafixpl prime, stravix and stravixpl, per square centimeter", to omit Stravix products, and to instead read: "Grafix PRIME® and GrafixPL PRIME, per square centimeter"; and request to establish a new Level II HCPCS code to identify Stravix and StravixPL.

Applicant's suggested language: "QXXXX Stravix, and StravixPL, per square centimeter."

**Agenda Item # 19**

**Application 19.068**

Request to establish a new Level II HCPCS code to identify acellular dermal matrix, Trade Name: Artia.

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 1**

**Application 19.009**

**TOPIC**

Request to modify existing Level II HCPCS code Q4163 which currently reads "Woundex, bioskin, per square centimeter" to include AxoBioMembrane.

Applicants suggested language: Q4163 "Amnion bio, WoundEX, AxoBioMembrane, per square centimeter."

**BACKGROUND**

Axolotl Biologix, Inc. submitted a request to revise existing HCPCS Level II code Q4163 which currently reads "Woundex, bioskin, per square centimeter" to instead read Amnion, WoundEX, AxoBioMembrane, per square centimeter.

According to the applicant, AxoBioMembrane is indicated for full and partial-thickness, chronic, acute, wounds and hard to heal wounds.

After preparation of the wound site, the human amnion allograft is surgically applied to the wound surface by the physician, extended beyond the wound margin and secured in place using the clinician's choice of fixation. AxoBioMembrane is available in 3 sizes; 1cm x 2cm, 2cm x 3cm, and 4cm x 4cm.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Amnion Bio or Axobiomembrane, per square centimeter."

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 1**

**Application 19.041**

**TOPIC**

Request to revise existing Level II HCPCS code Q4163 by adding Axolotl Graft and Axolotl DualGraft

Applicant's suggested language: Q4163 "WoundEX, BioSkin, Axolotl Graft, Axolotl DualGraft, per square centimeter."

**BACKGROUND**

Axolotl Bilologix, Inc., submitted a request to revise Level II HCPCS code Q4163 which currently reads "WoundEX, bioskin, per square centimeter" to include Axolotl Graft and Axolotl DualGraft.

According to the applicant, these products are "human amniotic allograft, decellularized, dehydrated placental membrane used as a wound barrier, nerve wrap, and serves as a selective membrane to allow for the repair or regeneration of damaged or diseased tissues."

According to the applicant, Axolotl DualGraft is a thicker version of the allograft for wound areas that are more vulnerable to damage. The product is available in four sizes; 1 x 2cm, 2 x 3cm, 4 x 4cm, and 4 x 6cm.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Axolotl Graft or Axolotl Dualgraft, per square centimeter."

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 1**

**Application 19.047**

**TOPIC**

Request to establish a single new Level II HCPCS code to identify human amniotic flowable allograft, intended for homologous use and to support the repair of soft tissue injury, Trade names: Axolotl Ambient and Axolotl Cryo.

Applicant's suggested language: QXXXX "Axolotl Ambient, Axolotl Cryo, per milliliter."

**BACKGROUND**

Axolotl Biologix, Inc. submitted a request to establish a new single Level II HCPCS code to identify Human amniotic flowable allografts, Trade names: Axolotl Ambient and Axolotl Cryo.

According to the applicant, Axolotl Ambient and Axololt Cryo are intended for homologous use and to support the repair of soft tissue injury.

The products are applied to the wound surface and/or injected into the wound margins. The products are available in 0.5 ml, 1 ml, and 2 ml dose sizes.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Axolotl Ambient or Axolotl Cryo, 0.1 mg."

**CMS HCPCS Public Meeting**

**Agenda Item # 2**

**Application 19.099**

**TOPIC**

Request to establish a new Level II HCPCS code to identify a human umbilical tissue membrane allograft, Trade Name: SurgiCORD

Applicant's suggested language: QXXXX "SurgiCORD per sq. cm."

**BACKGROUND**

Synergy Biologics, LLC submitted a request to establish a new Level II HCPCS code to identify SurgiCORD, a human umbilical tissue membrane allograft.

According to the applicant, indication for use of SurgiCORD is "intented neuropathic ulcers, venouus stasis ulcers, post-traumatic and pressure ulcers." "The minimally-processed allograft contains collagen types IV, V, and VII that will promote cellular differentiation and wound healing". SurgiCORD is applied topically to chronic, non-healing wounds. It is available in sizes: 1.5 x 1.5 cm, 3 x 2 cm, 3 x 4 cm and 3 x 6 cm.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Surgicord, per square centimeter."

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 2**

**Application 19.100**

**TOPIC**

Request to establish a new Level II HCPCS code to identify a bilayer human amniotic tissue allograft, Trade Name: SurgiGRAFT-DUAL

Applicant's suggested language: QXXXX "SurgiGRAFT-DUAL per sq. cm."

**BACKGROUND**

Synergy Biologics, LLC., submitted a request to establish a new Level II HCPCS code to identify SurgiGRAFT-DUAL, a bilayer human amniotic tissue allograft.

According to the applicant, SurgiGRAFT-DUAL is intended for use to repair or replace dermal tissue, including in the treatment of chronic, non-healing wounds including neuropathic ulcers, post-traumatic and pressure ulcers. The minimally-processed bilayer allograft contains collagen types IV, V, and VII that will promote cellular differentiation and wound healing. SurgiGRAFT-DUAL is applied topically to chronic, non-healing wounds. It is available in sizes 2 x 2 cm, 2 x 3 cm, 2 x 4 cm, 2 x 8 CM, 4 x 4 cm; and 12 mm, 15 mm and 18 mm diameter rounds.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Surgigraft-dual, per square centimeter."

**CMS HCPCS Public Meeting**

**Agenda Item # 3**

**Application 19.030**

**TOPIC**

Request to establish a new Level II HCPCS code to identify Novafix, a dehydrated human amniotic membrane allograft indicated for use in the management of wounds. Trade name: Novafix$^{TM}$.

Applicant's suggested language: QXXXX "Novafix$^{TM}$, per sq. cm."

**BACKGROUND**

A request was submitted on behalf of DCI Donor Services, Inc., to establish a new HCPCS Level II code to identify Novafix$^{TM}$.

According to the applicant, Novafix is indicated for use in the management of wounds, including: partial and full thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (e.g., donor sites, post-laser surgery, post-Mohs surgery, podiatric wounds and wound dehiscence), trauma wounds (abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.

Apply Novafix$^{TM}$ into the wound bed, and position as needed to completely contact the entire surface of the wound bed and extend slightly beyond wound margins. As medically necessary, Novafix$^{TM}$ can be secured to the wound site with the physician's preferred fixation method based on the type of wound, location of wound, patient's mobility and patient compliance. Novafix is supplied in sizes: 15mm disc, 2cm x 2cm, 4cm x 4cm, and 5cm x 5cm.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Novafix, per square centimeter."

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 4**

**Application 19.031**

**TOPIC**

Request to establish a new Level II HCPCS code to identify SurGraft, a "sheet-like" human amniotic membrane scaffold which "functions as a wound covering". Trade name: SurGraft®.

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

**BACKGROUND**

Surgenex, LLC, submitted a request to establish a new HCPCS Level II code to identify SurGraft®, a dehydrated human amniotic membrane allograft.

According to the applicant, SurGraft is "intended for the treatment of non-healing wounds and burn injuries". "SurGraft is directed for use in patients with acute or chronic wounds, including but not limited to, chronic, non-infected, diabetic foot ulcers, chronic, non-infected, partial or full-thickness diabetic foot skin ulcers (due to venous insufficiency), pressure ulcer, surgical wounds and burns which have not adequately responded to conventional therapy." The applicant also stated that "SurGraft is minimally manipulated Human Cell Tissue Product (HCT/P) intended for homologous use"

Surgraft is supplied in five sizes: 2 x 2 cm, 2 x 3, 2 x 4 cm and 4 x 8 cm.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Surgraft, per square centimeter."

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 5**

**Application 19.101**

**TOPIC**

Request to establish a new Level II HCPCS code to identify an Amniotic/Chorionic Tissue Allograft, Trade Name: AmnioWrap2

Applicant's suggested language: QXXXX "AmnioWrap2, per square cm."

**BACKGROUND**

A request was submitted on behalf of RegenTX Partners, LLC, to establish a new Level II HCPCS code to identify AmnioWrap2, an Amniotic/Chorionic Tissue Allograft.

According to applicant, AmnioWrap2 is intended for the treatment of wounds, including lower extremity ulceration caused by diabetes, chronic venous disease, and other chronic conditions. Acute wounds involving the dermal tissue layer may be appropriate for treatment with AnmioWrap2. AmnioWrap2 is provided dry in a double foil sterile pouch. It is available in various sizes, from 1 x 1 cm to 10 x 12 cm.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Amniowrap2, per square centimeter."

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 6**

**Application 19.033**

**TOPIC**

Request to revise existing Level II HCPCS code Q4163 which currently reads "Woundex, bioskin, per square centimeter"; to include "Membrane Graft and Membrane Wrap" human amniotic allograft membranes. Trade names: Membrane Graft and Membrane Wrap.

Applicant's suggested language: Q4163 "Amnion bio, WoundEX, Membrane Graft and Membrane Wrap, per square centimeter."

**BACKGROUND**

BioLab Sciences, Inc., submitted a request to revise existing Level II HCPCS code Q4163 to include Membrane Graft and Membrane Wrap. According to the applicant, Membrane Graft and Membrane Wrap are Human amniotic allograft membranes used to repair tissue deficits and to reduce healing time for chronic wounds and post-surgical wounds. "The patient population for use of the products includes children and adults suffering from non-healing acute and chronic wounds (diabetic, venous, mixed, venous-arterial, pressure ulcers), complex and /or open surgical wounds and burns."

The product is available in six sizes: 1 x 1cm, 1 x 2cm, 2 x 3cm, 4 x 4cm, 4 x 6cm, and 4 x 8cm.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Membrane Graft or Membrane Wrap, per square centimeter."

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**CMS HCPCS Public Meeting**

**Agenda Item # 6**

**Application 19.034**

**TOPIC**

Request to establish a single new Level II HCPCS code to identify Human amniotic flowable allografts. Trade names: Fluid Flow and Fluid GF.

Applicant's suggested language: QXXXX "Fluid Flow and Fluid GF, per milliliter."

**BACKGROUND**

BioLab Sciences, Inc. submitted a request to establish a single new Level II HCPCS code to identify Human amniotic flowable allografts. Trade names: Fluid Flow and Fluid GF.

According to the applicant, these products are intended for homologous use and support the repair of soft tissue injury by providing natural growth factors and other extracellular components to the injured area to promote healing, reduce inflammation, and reduce healing time. "The patient population indicated for use of Fluid Flow and Fluid GF include acute and chronic wounds and soft tissue injury, muscle and meniscus tears, ligament and tendon sprains, degenerative tissue disorders and Inflammatory conditions (tendonitis and fasciitis)."

The products are available in 0.5cc, 1cc and 2cc sizes.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Fluid Flow or Fluid Gf, 1 cc."

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**CMS HCPCS Public Meeting**

**Agenda Item # 6**

**Application 19.074**

**TOPIC**

Request to establish a new Level II HCPCS code to identify an autologous, homologous human skin product. Trade Name: MyOwn Skin$^{TM}$

Applicant's suggested language: QXXXX "MyOwn Skin$^{TM}$, per square centimeter."

**BACKGROUND**

BioLab Sciences, Inc., submitted a request to establish a new Level II HCPCS code to identify MyOwn Skin™, a fully autologous, homologous skin product. According to the applicant, MyOwn Skin™ is composed of a patient's own viable skin cells and contains extracellular matrix components to support cellular attachment and proliferation for tissue and skin repair.

MyOwn Skin™ is manufactured from a harvested sample of the patients' partial-thickness skin, composed of viable skin cells and an organized extracellular matrix. It is used to repair tissue deficits and to reduce healing time for chronic wounds and post-surgical wounds, with minimal to no rejection.

The product is available in a variety of sizes, ranging from 1 cm x 1 cm to 10 cm x 10 cm.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Myown Skin, Includes Harvesting and Preparation Procedures, per square centimeter."

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 7**

**Application 19.051**

**TOPIC**

Request to revise existing Level II HCPCS code Q4169 which identifies Artacent<sup>TM</sup> Wound to include single and dual layer products.

Applicant's suggested revised language: Q4169 "Artacent Wound, single or dual layer, per sq cm."

**BACKGROUND**

Tides Medical submitted a request to revise existing Level II HCPCS code Q4169, which currently reads: "Artacent wound, per square centimeter" to instead read: "Artacent wound, single or dual layer, per sq cm".

According to the applicant, "Artacent<sup>TM</sup> Wound is a dual or single layer human amniotic membrane allograft intended for treatment of acute and chronic wounds such as diabetic ulcers, venous stasis ulcers, burns, and additional wounds that are refractory to more conservative care."

Artacent<sup>TM</sup> Wound is applied to the wound bed following wound preparation. Absorbable/non-absorbable suture material and/or tissue adhesives may be used to apply the graft to the site, if necessary. Artacent<sup>TM</sup> Wound is supplied in a variety of sizes.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Existing code Q4169 "Artacent wound, per square centimeter", adequately describes the wound products as reflected in the FDA license.

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**Agenda Item # 7**

**Application 19.052**

**TOPIC**

Request to establish a new Level II HCPCS code to identify a "healing patch" comprised of Artacent Cord Human Umbilical Cord, Trade Name: Artacent Cord.

**BACKGROUND**

Tides Medical submitted a request to establish a new Level II HCPCS code to identify Artacent Cord.

According to the applicant, Artacent Cord is "a wound healing patch that is comprised of the umbilical cord." "It is intended for the treatment of acute and chronic wounds such as diabetic ulcers, venous stasis ulcers, burns, and additional wounds that are refractory to more conservative care."

Artacent Cord is applied to the wound bed following wound preparation. Absorbable/non-absorbable suture material and /or tissue adhesives may be used to apply the graft to the site, if necessary. Once applied the allograft can hydrated with sterile saline or other sterile solution, if needed.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Artacent cord, per square centimeter."

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**CMS HCPCS Public Meeting**

**Agenda Item # 8**

**Application 19.071**

**TOPIC**

Request to establish a new Level II HCPCS code to identify an umbilical cord allograft, Trade Name: Cellesta<sup>TM</sup> Cord.

Applicant's suggested language: QXXXX "Cellesta<sup>TM</sup> Cord, per square centimeter."

**BACKGROUND**

Ventris Medical, LLC, submitted a request to establish a new Level II HCPCS code to identify Cellesta™ Cord, an umbilical cord allograft product.

According to the applicant, Cellesta™ Cord is intended for use as a regenerative wound covering for the treatment of acute, chronic and surgically created wounds.

Cellesta™ Cord can be sutured, or glued, or laid over the desired tissue. It is available in 8 sizes: 3 circular and 5 rectangular: 12 mm, 15 mm, 18 mm, 1.5 x 1.5 cm, 3 x 2 cm, 3 x 4 cm, 3 x 6 cm, and 3 x 8 cm.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Cellesta cord, per square centimeter."

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CMS HCPCS Public Meeting

Agenda Item # 8

Application 19.072

**TOPIC**

Request to establish a new Level II HCPCS code to identify a dual layer human amniotic membrane allograft, Trade Name: Cellesta$^{TM}$ Duo.

Applicant's suggested language: QXXXX "Cellesta$^{TM}$ Duo, per square centimeter."

**BACKGROUND**

Ventris Medical, LLC, submitted a request to establish a new Level II HCPCS code to identify Cellesta™ Duo, a human amniotic membrane allograft. According to the applicant, Cellesta™ Duo is intended for use as a regenerative wound covering for the treatment of acute, chronic and surgically created wounds.

Cellesta™ Duo is available wet or dry in 5 different sizes: 2 x 2 cm, 2 x 4 cm, 2 x 6 cm, 3 x 3 cm, 4 x 4 cm, and 4 x 8 cm. Cellesta™ Duo is a dual allograft affixed to a layer of poly mesh. This can be sutured, or glued, or laid over the affected tissue.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Revise existing code Q4184 which currently reads "Cellesta, per square centimeter", to instead read "Cellesta or Cellesta Duo, per square centimeter". Revised code adequately describes Cellesta and Cellesta Duo and will be available for assignment by insurers if they deem appropriate.

**CMS HCPCS Public Meeting**

**Agenda Item # 9**

**Application 19.061**

**TOPIC**

Request to establish a new Level II HCPCS code to identify a human amnion allograft, Trade Name: AlloGen Liquid.

Applicants suggested language: QXXXX "AlloGen injectable, per ml."

**BACKGROUND**

Vivex Biomedical, Inc., submitted request to establish a new Level II HCPCS code to identify AlloGen.

According to the applicant, "AlloGen is composed of 100% human liquid amnion". It is "an amniotic fluid product derived from donated birth tissue... processed using aseptic techniques..." The allograft is exposed to electron beam radiation... to ensure terminal sterilization. "AlloGen is intended for treatment of non-healing wounds and burn injuries." The applicant claims that use of AlloGen liquid for the treatment of non-healing wounds and burn injuries is a homologous use in that. "Just as amniotic fluid protects and nourishes the fetus during development, AllGen provides the same protection to injured or traumatized tissue."

The dosage of AlloGen is per cubic centimeter (cc). It is intended for external application. It is supplied in single use vials ranging from 0.25 to 2.0 ml.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Allogen, per cc."

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**CMS HCPCS Public Meeting**

**Agenda Item # 10**

**Application 19.063**

**TOPIC**

Request to establish a new Level II HCPCS code to identify a "dehydrated cell and protein concentrate (dCPC) injectable derived from human amniotic fluid", Trade Name: Ascent$^{TM}$.

Applicant suggested language: Qxxxx "Ascent$^{TM}$, per milligram."

**BACKGROUND**

StimLabs, LLC, submitted a request to establish a new Level II HCPCS code to identify Ascent$^{TM}$, a dehydrated cell and protein concentrate (dCPC) injectable derived from human amniotic fluid. According to the applicant, Ascent$^{TM}$ combines a selected set of cells from amniotic fluid and their components, including TIMPs, growing factors, interleukins and hyaluronic acid. Through complex interactions, these components work together to provide protecting, cushioning, lubrication, and inflammation reduction at the site of injury. Ascent$^{TM}$ is intended for the treatment of non-healing wounds and burn injuries. Ascent$^{TM}$ is offered in 7.5 mg, 15 mg, and 30 mg powdered weight. The suggested reconstitution volumes are 0.5 cc, 1 cc, and 2 cc respectively giving a 0.75%, 1.5% and 3% dose. Ascent$^{TM}$ is reconstituted using sterile saline based on recommended reconstitution amounts.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Ascent, 0.5 mg."

**CMS HCPCS Public Meeting**

**Agenda Item # 11**

**Application 19.088**

**TOPIC**

Request to establish a single new Level II HCPCS code to identify WoundFix<sup>TM</sup> Membrane BioWound<sup>TM</sup> Membrane.

Applicant's suggested language: Q41XX "WoundFixTM Membrane & BioWoundTM Membrane, per square centimeter."

**BACKGROUND**

A request was submitted on behalf of Human Regenerative Technologies, LLC, to establish a single new Level II HCPCS code to identify human amnion-based membranes: WoundFix<sup>TM</sup> and BioWound<sup>TM</sup>

According to the applicant, WoundFix<sup>TM</sup> and BioWound<sup>TM</sup> membranes are single-layer wound coverings for common wounds. These are intended for use as a wound covering, surgical covering, wrap or barrier, application to partial-and full-thickness, acute and chronic wounds such as, traumatic and complex wounds, burns, surgical and Mohs surgery sites and diabetic, venous, arterial, pressure and other ulcers, including with exposed tendon, muscle, bone, or other vital structures.

These products are supplied in single use packaging in sizes ranging from .786 to 486 sq. cm.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Woundfix, Biowound, Woundfix Plus, Biowound Plus, Woundfix Xplus or Biowound Xplus, per square centimeter."

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 11**

**Application 19.089**

**TOPIC**

Request to establish a single new Level II HCPCS code to identify human, chorion-based membranes. Trade Names: WoundFixTM Plus Membrane and BioWoundTM Plus Membrane

Applicant's suggested language: Q41XX "WoundFixTM Plus Membrane & BioWoundTM Plus Membrane, per square centimeter."

**BACKGROUND**

A request was submitted on behalf of Human Regenerative Technologies, LLC, to establish a single new Level II HCPCS code to identify human, chorion-based membranes: WoundFix[TM] Plus and BioWound[TM] Plus.

According to the applicant, WoundFix[TM] Plus and BioWound[TM] Plus membranes are single layer wound coverings intended for use as a wound covering, surgical covering, wrap or barrier, application to partial-and full-thickness, acute and chronic wounds such as traumatic and complex wounds, burns, surgical and Mohs surgery sites and diabetic, venous, arterial, pressure and other ulcers, including with exposed tendon, muscle, bone, or other vital structures.

Typically, one application is applied per wound; however, the product may be reapplied if necessary. WoundFix[TM] Plus and BioWound[TM] Plus membrane are supplied in single use packaging in sizes ranging from .786 to 192 sq. cm.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Woundfix, Biowound, Woundfix Plus, Biowound Plus, Woundfix Xplus or Biowound Xplus, per square centimeter."

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 11**

**Application 19.090**

**TOPIC**

Request to establish a single new Level II HCPCS code to identify human placental tissue based membranes. Trade Names: WoundFix<sup>TM</sup> XPlus Membrane and BioWound<sup>TM</sup> XPlus Membrane.

Applicant's suggested language: Q41XX "WoundFix<sup>TM</sup> XPlus Membrane & BioWound<sup>TM</sup> XPlus Membrane, per square centimeter."

**BACKGROUND**

A request was submitted on behalf of Human Regenerative Technologies, LLC, to establish a single new Level II HCPCS code to identify WoundFix<sup>TM</sup> XPlus Membrane and BioWound<sup>TM</sup> XPlus human placental tissue-based membranes.

According to the applicant, WoundFix<sup>TM</sup> XPlus Membrane and BioWound<sup>TM</sup> XPlus Membrane are single layer wound coverings intended to be used as a wound covering, surgical covering, wrap or barrier, application to partial-and full-thickness, acute and chronic wounds such as, traumatic and complex wounds, burns, surgical and Mohs surgery sites and diabetic, venous, arterial, pressure and other ulcers, including with exposed tendon, muscle, bone, or other vital structures.

WoundFix<sup>TM</sup> XPlus Membrane and BioWound<sup>TM</sup> XPlus Membrane are supplied in single-use packaging, in 6 sq. cm and 12 sq. cm. sizes.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Woundfix, Biowound, Woundfix Plus, Biowound Plus, Woundfix Xplus or Biowound Xplus, per square centimeter."

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 12**

**Application 19.036**

**TOPIC**

Request to establish a new Level II HCPCS code to identify a human acellular dehydrated dermis regenerative tissue matrix. Trade name: BellaCell HD.

Applicant's suggested language: "BellaCell HD Regenerative Tissue Matrix, per square centimeter."

**BACKGROUND**

HansBiomed Corp., submitted a request to establish a new HCPCS Level II code to describe BellaCell HD, a human acellular dehydrated dermis regenerative tissue matrix.

According to applicant, BellaCell HD is indicated "for use in skin reconstruction to repair skin loss from burn injuries, congenital diseases, abdominal wall repair, hiatal hernia repair, breast reconstruction, and ulcers or malformation."

BellCell HD is supplied as 1.0-1.39mm, 1.4-1.79mm, 1.8-2.29mm, 2.3-2.99mm and 3.0-3.49mm

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Bellacell HD or Surederm, per square centimeter."

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 12**

**Application 19.037**

**TOPIC**

Request to establish a new Level II HCPCS code to identify a human acellular dermal matrix. Trade name: SureDerm.

Applicant's suggested language: "SureDerm Acellular Dermal Matrix, per square centimeter."

**BACKGROUND**

HansBiomed Corp., submitted a request to establish a new HCPCS Level II code to identify SureDerm Acellular Dermal Matrix.

According to applicant, SureDerm is indicated for use in "skin reconstruction to repair skin loss from burn injuries, car accidents, congenital diseases, periodontal diseases, urinary incontinence, and ulcers or malformations."

SureDerm is supplied as 0.25-0.59mm, 0.6-0.99mm, 1.0-1.39mm, 1.4-1.79mm and 1.8mm and over

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Bellacell HD or Surederm, per square centimeter."

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**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 13**

**Application 19.055**

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**TOPIC**

Request to establish a new Level II HCPCS code to identify Human Keratin Matrix derived from human hair. Trade Name: ProgenaMatrix™.

**BACKGROUND**

A request was submitted on behalf of Cell Constructs I, LLC, to establish a new Level II HCPCS code to identify a graft matrix composed of human keratin proteins selectively extracted from human hair. Trade Name: ProgenaMatrix™

According to the applicant, "ProgenaMatrix™ is indicated for dry and exuding partial and full thickness wounds such as pressure (stage I-IV) and venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, donor sites and grafts, first and second-degree burns, superficial injuries, cuts,, abrasions and surgical wounds."

ProgenaMatrix™ is applied directly to the wound bed after debridement of the wound site to remove necrotic debris, biofilm, and non-viable tissue. Each matrix provides the same amount of human keratin proteins per square centimeter of product. It is supplied in sizes: 2cm x 2cm, 4cm x 4cm, 6cm x 6cm 10cm x 10cm; and 12cm x 12cm.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Establish Q42XX "Progenamatrix, per square centimeter."

# CMS HCPCS Public Meeting

# Agenda Item # 14

## Application 19.059

## TOPIC

Request to revise existing Level II HCPCS code Q4165 "Keramatrix, per square centimeter" to add an additional similar product, Kerasorb.

Applicant's suggested language: Q4165 "Keramatrix, per square centimeter or Kerasorb Wound Matrix, per square centimeter."

## BACKGROUND

A request was submitted on behalf of Keraplast Research Limited, to revise existing Level II HCPCS code Q4165 which currently reads: "Keramatrix, per square centimeter" to instead read: "Keramatrix, per square centimeter or Kerasorb Wound Matrix, per square centimeter".

According to the applicant, "Kerasorb Wound Matrix is clinically indicated for the patient population with the following types of chronic wounds: pressure ulcers (stages I-IV), venous stasis ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, and donor sites and grafts."

Kerasorb is supplied in single use pouches containing one 10 cm x 10 cm foam wound matrix. It is applied to the wound area using aseptic technique similar to Keramatrix and other cellular and /or tissue based products for the skin wounds.

## PRELIMINARY HCPCS CODING RECOMMENDATION

Revise existing code Q4165, which currently reads "Keramatrix, per square centimeter", to instead read "Keramatrix or Kerasorb, per square centimeter". Revised code Q4165 adequately describes Keramatrix and Kerasorb and will be available for assignment by insurers if they deem appropriate.

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 15**

**Application 19.095**

**TOPIC**

Request to revise existing Level II HCPCS code Q4122, which currently reads: "DermACELL, per square centimeter" to instead read: "DermACELL, DermACELL AWM, DermACELL AWM Porous, per square centimeter."

**BACKGROUND**

LifeNet Health submitted a request to revise existing Level II HCPCS code Q4122, which currently reads: "DermACELL, per square centimeter" to instead read: "DermACELL, DermACELL AWM, DermACELL AWM Porous, per square centimeter."

According to applicant, DermACELL, DermACELL AWM, DermACELL AWM Porous "are decellularized human dermal allografts" indicated for use in "chronic non-healing wounds such as diabetic and venous leg ulcers, acute burns, breast reconstruction and other associated soft tissue injuries."

The grafts comes in various sizes, from 4 to 320 square centimeters and from 0.2 - 3.5 mm thick.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Revise existing code Q4122, which currently reads, "Dermacell, per square centimeter", to instead read "Dermacell, Dermacell Awm or Dermacell Awm Porous, per square centimeter". Revised code Q4122 adequately describes Dermacell, Dermacell Awm or Dermacell Awm Porous, and will be available for assisgnment by insurers if they deem appropriate.

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**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 16**

**Application 19.070**

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**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, 0.5cc."

**BACKGROUND**

The Musculoskeletal Transplant Foundation submitted a request to establish a new Level II HCPCS code to identify Renuva®, an Allograft Adipose Matrix, derived from processed donated human adipose tissue.

According to the applicant, "Renuva is intended for the replacement of damaged or inadequate integumental adipose tissue matrix such as facial deformities, craniofacial deformities, breast reconstructions, or for other homologous uses into areas of the body where native fat would exist. Renuva® Allograft Adipose Matrix may also be used for the reinforcement or supplemental support in underlying adipose tissue matrix as the result of damage or naturally occurring defects e.g., cleft lip, Parry-Romberg syndrome, and facial LDS." The matrix is dehydrated and must be rehydrated prior to use. When ready to use, the allograft is injected into the site subcutaneously. The matrix is available in three sizes: 1.5cc, 3cc and 5cc tissue package.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

The CMS spent a significant amount of time carefully considering this application and in the process, communicated with the applicant several times, in February, March and April of this year, and researching policy information and other supplemental materials provided by the applicant. Yet CMS was unable to find policy on the part of any insurance sector that would indicate a need for a code to identify a non-autologous adipose graft for the clinical indications specified by the applicant, in a physician's office setting.

**CMS HCPCS Public Meeting**

**Agenda Item # 17**

**Application 19.004**

**TOPIC**

Request to establish a single new Level II HCPCS code to identify a 100% native, freeze-dried, Type-I bovine Collagen matrix for use for wound management, Trade names: ACM Surgical Collagen and ACM Surgical Extra Advanced Collagen.

Applicant's suggested language: QXXXX "ACM Surgical Collagen/ACM Surgical Extra Advanced Collagen, per square centimeter."

**BACKGROUND**

A request was submitted on behalf of Human Biosciences Inc., to establish a new level II HCPCS code to identify ACM Surgical Collagen and ACM Surgical Extra Advanced Collagen, 100% native, freeze- dried, type-1 bovine collagen matrix, provided in a collagen sheet configuration.

According to the applicant, ACM Surgical Collagen and ACM Surgical Extra Advanced Collagen are indicated for use as a scaffold in the "management of partial and full-thickness wounds [i.e. surgical wounds, donor sites, graft sites, second degree burns, traumatic wounds (pressure, venous, mixed vascular etiologies, diabetic ulcers)] to support healing".

ACM Surgical Collagen and ACM Surgical Extra Advanced Collagen is administered by applying each individual matrix directly to the wound surface after preparation of the wound site to remove necrotic debris, bioflim, and non-viable tissue, using the clinician's choice of fixation. Each matrix provides the same amount of collagen per square centimeter of product. Usually one tissue is applied per application. Additional applications may be required, based on physician choice. These products are packaged in sterile, single-use pouches and available in sheet sizes: 2"x2", 4"x4", 4"x5", 7x7", 8"x12".

**PRELIMINARY HCPCS CODING RECOMMENDATION**

Existing codes A6021 "Collagen dressing, sterile, size 16 square inch or less, each", A6022 "Collagen dressing, sterile, size more than 16 sq inch but less than or equal to 4 sq. in., each", or A6023 "Collagen dressing, sterile, size more than 48 sq in., each", depending on size, adequately describes ACM Surgical collagen and ACM Surgical extra advanced collagen. These codes are available for assignment by insurers if they deem appropriate.

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 17**

**Application 19.113**

## TOPIC

Request to establish a new Level II HCPCS code to describe a 100% native Type 1 bovine collagen powder for use in wound management, Trade Name: ACM Surgical Extra Advanced Collagen Powder.

Applicants suggested language: QXXXX "ACM Surgical Extra Advance Collagen Powder, per gm."

## BACKGROUND

A request was submitted on behalf of Human Biosciences, to establish a Level II HCPCS code to identify ACM Surgical Extra Advanced Collagen Powder.

According to the applicant, ACM Surgical Extra Advanced Collagen Powder "is indicated for wound management of partial and full-thickness wounds such as second degree burns, ulcers (pressure, venous, mixed vascular etiologies, diabetic ulcers) and other wounds (e.g. surgical wounds, scrapes, traumatic wounds)."

The product is applied directly to the wound surface after preparation of the wound site to remove necrotic debris, biofilm, and non variable tissue. It is supplied as sterile, single-use 1gm pouch, 1gm vial, 5gm vial and 10gm bottle.

## PRELIMINARY HCPCS CODING RECOMMENDATION

Existing code A6010 "Collagen based wound filler, dry form, sterile, per gram of collagen", adequately describes ACM surgical extra advanced collagen powder and is available for assignment by insures if they deem appropriate.

**TOPIC**

Request to revise existing Level II HCPCS code Q4133 which currently reads: "Grafix prime, grafixpl prime, stravix and stravixpl, per square centimeter", to omit Stravix products, and to instead read: "Grafix PRIME® and GrafixPL PRIME, per square centimeter"; and request to establish a new Level II HCPCS code to identify Stravix and StravixPL.

Applicant's suggested language: "QXXXX Stravix, and StravixPL, per square centimeter."

**BACKGROUND**

Osiris Therapeutics, Inc., submitted a request to un-do the result of its prior year application to include Stravix and Grafix products in the same code; and to instead create a coding distinction between the Stravix and Grafix. Specifically, in the current coding cycle, Osiris asked CMS to establsih a new Level II HCPCS code to identify Stravix® and StravixPL™; and to revise the descriptor of existing code Q4133 "Grafix prime, grafixpl prime, stravix and stravixpl, per square centimeter", to omit Stravix, and Stravix PL, on the basis that Stravix products are thicker than Grafix and that insurers treat that product differently.

According to applicant Grafix prime, GrafixPL prime and Stravix/StravixPL are both placental tissue allografts indicated for use on wound repair for the following indications: diabetic foot ulcer, venous leg ulcers, pressure ulcers, dehisced surgical wounds, burns, acute surgical wounds, pyoderma gangrenosum, and epidermolysis bullosa, including complex wounds with exposed bone, tendon and hardware, and chronic recalcitrant wounds of various etiologies in peripheral arterial disease (PAD). Specifically, Stravix/StraviPL are used for deeper wounds in higher risk patients and the wounds located in areas subject to high shear force. The quantity and size of the product used will vary based upon wound size and physician recommendation. Stravix/StravixPL are approximately 10 times thicker than Grafix PRIME and GrafixPL PRIME and dosing recommendation is weekly for up to 12 weeks or until the wound is closed.

**PRELIMINARY HCPCS CODING RECOMMENDATION**

CMS supports its 2018-2019 coding cycle decision honoring Osiris' prior request to include Grafix and Stravix products together in existing code Q4133. Existing code Q4133 "Grafix prime, grafixpl prime, stravix and stravixpl, per square centimeter", adequately describes the Stravix and Grafix products that are subject to this application.

**May 13, 2019**

**CMS HCPCS Public Meeting**

**Agenda Item # 19**

**Application 19.068**

## TOPIC

Request to establish a new Level II HCPCS code to identify acellular dermal matrix, Trade Name: Artia.

## BACKGROUND

Allergan USA Inc. submitted a request to establish a new Level II HCPCS code to identify Artia™, a sterile, acellular dermal matrix (ADM) developed for use in plastic and reconstructive surgery, specifically designed to have handling characteristics and biologic response similar to Alloderm™ Regenerative Tissue Matrix. It is manufactured by Allergan USA Inc.

According to the applicant, Artia™ is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes, which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

Based on each individual patient case, the physician will determine the most appropriate size and shape of Artia™ to use on the patient. Artia™ is implanted in a surgically created subcutaneous space during plastic and reconstructive procedures, and is sutured to the patient's own adjacent soft tissue under appropriate physiologic tension.

## PRELIMINARY HCPCS CODING RECOMMENDATION

Artia is not suitable for coding in Level II HCPCS as it is used exclusively in hospital inpatient and outpatient settings. For inpatient use, Artia would be bundled in hospital payment. CMS re-refers applicant to CMS' pass-through coding program for consideration of pass-through coding for use HOPPS settings.