



## **Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries**

### **Supplemental 2021 HCPCS Coding Cycle**

This document presents a summary of each HCPCS code application and CMS' HCPCS coding decisions for deferred applications for ten 510(k)-cleared wound care products processed during CMS' 2020 and 2021 HCPCS code application review cycles. It also includes one HCPCS code application and CMS' HCPCS coding decision for a product that qualifies for the Transitional Adjustment for New and Innovative Equipment and Supplies under the End-Stage Renal Disease Prospective Payment System.

Each individual summary includes: the request number; topic; a summary of the applicant's request as written by the applicant with occasional, non-substantive editorial changes made by CMS for clarity.

The coding actions described in this document will become effective on January 1, 2022.

The HCPCS coding decisions below will also be included in the January 2022 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at:

<https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

For inquiries regarding coverage, please contact to the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' national coverage determination process, refer to information published at:

<https://www.cms.gov/Medicare/Coverage//DeterminationProcess>

<https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center>.

## Request # 20.111

### Topic/Issue

Request to establish a new HCPCS Level II code to identify NovoSorb SynPath.

Applicant's suggested language: QXXXX “NovoSorb SynPath Dermal Matrix.”

### Applicant’s Summary

PolyNovo North America, LLC requested to establish a new HCPCS Level II code to identify NovoSorb SynPath.

NovoSorb SynPath is a sterile, acellular, synthetic dermal matrix made from the proprietary NovoSorb technology. The porous network of non-toxic, biodegradable synthetic polymers acts as a template to support the proliferation of vital cells involved in cellular repair. As the matrix integrates into the wound bed, it supports the creation of a neodermal structure. The fenestrated matrix allows excess exudate from the wound to pass through to a secondary absorbent dressing to prevent maceration. The matrix is covered by a sealing membrane that reduces water vapor loss, helps maintain a moist wound environment, and acts as a barrier to prevent external contamination of the wound. The membrane remains intact with the dermal matrix until the clinician determines when to remove it based on the wound progression, the need for surgical closure or grafting, or application of another dermal template. It is indicated for management of partial and full thickness wounds, chronic ulcers (pressure, venous, diabetic), surgical wounds, and traumatic wounds. The device provides a dermal template to support the development of a neodermis for wound healing. Dosing does not apply to the device. After preparing the wound site, the clinician applies the textured side of the matrix directly into the wound surface flush against the wound bed. The device can be further fenestrated with a scalpel to facilitate drainage. The clinician secures the matrix using their choice of fixation. The product is presented in a sterile, inner transparent pouch encased by an outer aluminized pouch. The product is available in a range of sizes from 2cm x 2cm square to 20cm X 40cm square.

There is no current HCPCS code to describe an acellular, biodegradable synthetic polymer-based template (dermal matrix) with a sealing membrane for cellular repair of wounds.

### Final Decision

Establish a new HCPCS Level II code A2006 “Novosorb synpath dermal matrix, per square centimeter”

## Request # 20.120

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Restrata Wound Matrix.

Applicant's suggested language: Q42XX "Restrata per square centimeter."

### Applicant's Summary

Acera Surgical, Inc. requested a unique HCPCS Level II Q code to describe Restrata Wound Matrix, a fully-synthetic, nanofiber wound matrix.

Restrata functions as a matrix for treating wounds and is engineered utilizing nano-scale materials to provide a resorbable scaffolding to initiate cell migration, revascularization, and soft tissue formation and reinforcement in the prepared wound bed. CMS classifies Restrata as a skin substitute: "We have determined that the product may be treated as a skin substitute for Medicare payment purposes." Restrata is currently described by the code C1849 Skin substitute, synthetic, resorbable, per square centimeter. This code can be used by hospitals to report use of Restrata but is not recognized by Medicare in other sites of service, including sites which are paid under the Medicare Physician Fee Schedule, such as physician offices and ambulatory wound care clinics. Restrata will commonly be administered in those sites of service and a product-specific Q code, comparable to the codes available for other skin substitute products, is necessary to report the product. The HCPCS codes previously assigned by CMS in response to Acera's 2018 HCPCS application, A6460 and A6461, do not appropriately describe the product, which functions like other skin substitutes and is implanted by a physician into the wound bed, and completely resorbed into the wound. Additional product applications follow as clinically necessary and prescribed by the provider. Restrata is indicated for use in management of wounds, including partial and full thickness wounds, pressure sores, venous, diabetic and chronic vascular ulcers, wounds with tunneling or undermining, surgical (e.g. donor site/grfts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma and draining wounds. The fibrous structure of Restrata is highly porous. It has a structure similar to native extracellular matrix of the skin and has a defined rate of resorption which provides a scaffold for cellular infiltration and vascularization before completely degrading via hydrolysis in the wound bed. Restrata permits the migration of cells and formation of soft tissue in the wound bed and does not contain any human or animal materials or tissues. The dosage includes size selection appropriate to the prepared wound bed and is reapplied every 7 days or as necessary. The product is cut to the desired shape of the wound bed and hydrated before being anchored securely using the physician's preferred fixation method based on wound type/location. Restrata is supplied in a single use double peel package in a variety of sizes. The applicant also requested that CMS delete HCPCS codes A6460 and A6461 as they serve no purpose and may create confusion.

### Final Decision

Establish a new HCPCS Level II code A2007 "Restrata, per square centimeter"

## **Request # 20.200**

### **Topic/Issue**

Request to establish a new HCPCS Level II code to identify Symphony, an extracellular matrix bioengineered skin substitute derived from ovine forestomach tissue and including hyaluronic acid.

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

### **Applicant's Summary**

Symphony is a bioengineered skin substitute composed of extracellular matrix (ECM) and hyaluronic acid (HA). Symphony contains three layers of ovine-derived ECM, which contains more than 150 essential ECM proteins, including structural proteins, adhesion proteins, and signaling proteins—all of which aid the wound healing process. A single layer of HA has been included in the composite design to provide additional healing biology and ensure a moist wound environment that is critical to healing. The composite design scaffolds the patient's own cells to rebuild dermal tissues in acute and chronic wounds.

### **Final Decision**

Establish a new HCPCS Level II code A2009 "Symphony, per square centimeter"

## **Request # 21.007**

### **Topic/Issue**

Request to establish a new HCPCS Level II code to identify InnovaMatrix AC.

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

### **Applicant's Summary**

InnovaMatrix AC is a sterile, single use, medical device consisting of extracellular matrix derived from porcine placental material used for safe and effective wound treatment. InnovaMatrix AC is composed of collagen, elastin, laminin, fibronectin, hyaluronic acid and sulfated glycosaminoglycans. This biodegradable wound matrix provides a protective cover to the wound.

There are no current specific HCPCS codes that define a skin substitute composed of an extracellular matrix derived from porcine placental material. InnovaMatrix AC is the first Food and Drug Administration cleared medical device sourced from pig placenta. Therefore, we request a new HCPCS code category code: Q4XXX "InnovaMatrix AC, per sq. cm" to facilitate proper billing and coding to all payers in the full range of site of care settings.

InnovaMatrix AC is intended for use in the management of wounds, including: partial- and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor site/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds, (abrasions, lacerations, second-degree burns and skin tears), and draining wounds. It is applied on a wound after the wound bed is prepared with standard debridement methods. The product will fully resorb and does not have to be removed. InnovaMatrix AC is supplied terminally sterile, in a single use package, and in a variety of sizes.

### **Final Decision**

Establish a new HCPCS Level II code A2001 "Innovamatrix ac, per square centimeter"

## **Request # 21.010**

### **Topic/Issue**

Request to establish a new HCPCS Level II code to identify Mirragen Advanced Wound Matrix.

Applicant's suggested language: Q42XX "Mirragen Advanced Wound Matrix, per square centimeter."

### **Applicant's Summary**

Mirragen Advanced Wound Matrix is composed solely of biocompatible and resorbable borate-based bioactive glass fibers and particulates. It is intended for use in the management of wounds. The product size varies from 1"x1" to 4"x4" and the size is selected according to the wound dimensions. The device is a synthetic resorbable matrix that covers the wound, absorbs exudate, and provides a scaffold upon which cellular migration, revascularization, and soft tissue regeneration can occur within the wound bed. The fiber structure of MIRRAGEN mimics the microstructure of the extracellular matrix, thereby functioning as a skin substitute in the wound healing process.

### **Final Decision**

Establish a new HCPCS Level II code A2002 "Mirragen advanced wound matrix, per square centimeter"

## **Request # 21.020**

### **Topic/Issue**

Request to establish a new HCPCS Level II code to identify TheraGenesis.

Applicant's suggested language: Q42XX "TheraGenesis, per sq. cm."

### **Applicant's Summary**

TheraGenesis is a bilayer wound matrix, meshed and non-meshed. TheraGenesis is a cellular and/or tissue-based product (CTP) that is comprised of two layers: a porcine tendon-derived atelo-collagen layer and a silicone film layer. The silicone film layer also contains a non-adhesive mesh (TRES) to reinforce the silicone film to better hold sutures and staples to adhere TheraGenesis to the wound being treated. The biodegradable collagen matrix provides a scaffold for cellular and capillary in-growth. TheraGenesis will be used to treat patients with chronic and traumatic wounds including but not limited to diabetic foot ulcers, venous leg ulcers, burns, and other chronic and traumatic wounds and tissue deficits, in outpatient wound care clinics, outpatient and inpatient operating rooms, ambulatory surgical centers and physician offices sites of service. TheraGenesis is a single-use, bi-layered wound matrix that is administered by a physician as a wound covering to aid in the repair or replacement of lost or damaged tissue.

### **Final Decision**

Establish a new HCPCS Level II code A2008 "Theragenesis, per square centimeter"

## Request # 21.022

### Topic/Issue

Request to establish a new HCPCS Level II code to identify XCelliStem.

The applicant did not provide recommended language for the requested new code.

### Applicant's Summary

XCelliStem is a proprietary blend of multiple ECM source material, spleen and lung. It is the only product composed of multiple ECM sources. All current products are from a single ECM source and their composition is limited based on the sole source material. Each ECM source material is composed of a unique collection of varying components, such as collagen, elastin, fibronectin, laminin, glycosaminoglycans (GAGs), proteoglycans, and other proteins. Utilizing multiple ECM sources allows for a final composition that contains a broader diverse mix of various ECM components. ECM components have a variety of signaling molecules contained within them, and also have a multitude of binding sites within their structure. Binding sites and signaling molecules can be involved in a wide array of activities within tissue, including binding to existing native ECM material, binding to cells, signaling cell attraction, cell mobility, cell growth, and cell differentiation. Signaling components can also be involved in progenitor cell recruitment to the site, and regulation of progenitor cell activity at the site.

### Final Decision

Establish a new HCPCS Level II code A2004 "Xcellistem, 1 mg<sup>1</sup>"

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<sup>1</sup> Update 4/6/2022: Revised the final code descriptor language for Request # 21.022 from "Xcellistem, per square centimeter" to "Xcellistem, 1 mg"

## Request # 21.024

### Topic/Issue

Request to establish a new HCPCS Level II code to identify Microlyte Matrix and a request to delete Microlyte Matrix from the A6460 HCPCS code.

The applicant did not provide recommended language for the requested new code.

### Applicant's Summary

Imbed Biosciences, Inc. submitted a request to establish a new HCPCS Level II code for Microlyte Matrix and delete Microlyte Matrix from A6460.

Microlyte Matrix is composed of an ultrathin polyelectrolyte multilayer matrix coated with a resorbable polymer. It functions as a wound matrix product to enhance wound granulation and maintain a moist wound healing environment which facilitates cell growth, neovascularization, and wound closure. The matrix components of Microlyte serve as a functional molecular template to facilitate the granulation process by masking the disorganized surface chemistry of the wound bed. Microlyte Matrix is currently assigned HCPCS A6460, a code which CMS created for a product now assigned to C1849 "Skin substitute, synthetic, resorbable, per sq. cm". In the CY 2021 OPSS Final Rule, CMS defined skin substitutes as "a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers" and that they are products that are "applied to wounds to aid in healing and through various mechanisms of action." Imbed has requested formal assignment to C1849, which accurately describes Microlyte Matrix and its clinical function. While this code may be billed in hospital outpatient departments, it is not recognized by Medicare in other places of service including physician offices. We therefore request that Microlyte Matrix be assigned a unique Q-code and be deleted from code A6460. Microlyte Matrix may be used for the management of: wounds; partial and full thickness wounds including pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second-degree burns, abrasions and lacerations, donor sites and surgical wounds; and may be used over debrided and grafted partial thickness wounds. The product is applied to wounds as a dry, flexible polymer film; the product size is determined by wound size. Microlyte Matrix is supplied individually packaged in foil pouches in varying sizes.

### Final Decision

Establish a new HCPCS Level II code A2005 "Microlyte matrix, per square centimeter"

## **Request # 21.073**

### **Topic/Issue**

Request to establish a new HCPCS Level II code to identify Apis.

Applicant's suggested language: QXXXX “Apis, a bioengineered skin and soft tissue (skin substitute) device, absorbable, per square centimeter”

### **Applicant’s Summary**

Apis is a 510(k)-cleared skin and soft tissue (skin substitute) device. Apis is fully absorbable, biodegradable and manufactured through a proprietary synthesis of three materials. Depending on wound characteristics, multiple applications of Apis may be appropriate as degradation occurs. Gelatin, a porcine collagen derivative, is the primary material accounting for greater than 50% of the Apis composition. The two other materials are Manuka honey and hydroxyapatite. The FDA cleared Apis on May 31, 2019. Apis is currently marketed and available for use in the United States. It was first marketed in the United States during the second half of 2019, and was first sold in December 2019.

### **Final Decision**

Establish a new HCPCS Level II code A2010 “Apis, per square centimeter”