



2017

Reimbursement and Coding Guide





Table of Contents

Product Description.....	2
Indication for Use.....	2
Please Refer to Product Label for Full Instructions for Use.....	2
Skin Replacement Procedures.....	3
Chronic Wound Treatment Procedures.....	4
Physicians'.....	4
Hospital Outpatient and Ambulatory Surgical Center (ASC).....	5
Procedure Payment.....	5
HCPCS Codes and Modifiers.....	5
Company Information.....	6



Product Description

The Restrata® Wound Matrix is a sterile, single use device intended for use in local management of wounds. The Restrata™ Wound Matrix is a soft, white, conformable, non-friable, absorbable matrix that acts as a protective covering for wound defects, providing a moist environment for the body's natural healing process to occur. Restrata® is made from synthetic biocompatible materials and was designed to include a fibrous structure with high porosity, similar to native extracellular matrix. Restrata® is a porous matrix with a defined rate of resorption that provides a scaffold for cellular infiltration and vascularization before completely degrading via hydrolysis. The device permits the ingress of cells and soft tissue formation in the defect space / wound bed. The device does not contain any human or animal materials or tissues.

Restrata® is available in the following sizes:

Part Number	Size
RWM1-1X1	2.5 cm x 2.5 cm (1 in. x 1 in.)
RWM1-1X3	2.5 cm x 7.5 cm (1 in. x 3 in.)
RWM1-2X2	5.0 cm x 5.0 cm (2 in. x 2 in.)
RWM1-3X3	7.5 cm x 7.5 cm (3 in. x 3 in.)
RWM1-4X5	10.0 cm x 12.5 cm (4 in. x 5 in.)

Indication for Use

Please Refer to Product Label for Full Instructions for Use

Restrata® Wound Matrix is intended 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 site / grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence)
- Trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears)
- Draining wounds



Skin Replacement Procedures

CPT®	Description
15002	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq. cm or 1% of body area of infants and children
15003	each additional 100 sq. cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)
15005	each additional 100 sq. cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)

These codes are not intended to be reported for simple graft application alone or application stabilized with dressings (e.g., by simple gauze wrap). The *Restrata® Wound Matrix* is anchored using the surgeon's choice of fixation. When services are performed in the office, the *Restrata® Wound Matrix* product should be reported separately. Routine dressing supplies are not reported separately



Chronic Wound Treatment Procedures

When used as a Bioengineered Skin Substitute, treatments using *Restrata® Wound Matrix* are reported under CPT code range 15271-15278 for topical application to a wound surface in a) physician office setting, and for high cost Bioengineered Skin Substitutes (also referred to as CTPs - Cellular or Tissue Based Products) – those whose cost exceeds \$30.00 per sq. cm. This cost threshold is set by Medicare and changes annually. Some, but not all private insurers apply similar criteria.

Physicians' Office

CPT ©	Description	Physician Facility: 2017 National Average Payment ¹	Physician Non- Facility (office): 2017 National Average Payment ¹
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq. cm; first 25 sq. cm or less wound surface area	\$87.57	\$142.84
+15272	Each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	\$17.94	\$27.63
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq. cm; first 100 sq. cm wound surface area, or 1% of body area of infants and children	\$210.67	\$306.49
+15274	Each additional 100 sq. cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	\$47.73	\$73.21
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq. cm; first 25 sq. cm or less wound surface area	\$99.05	\$151.81
+15276	Each additional 25 sq. cm wound surface area, or part thereof (List separately in addition to code for primary procedure)	\$26.20	\$35.53
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq. cm; first 100 sq. cm wound surface area, or 1% of body area of infants and children	\$236.15	\$334.12
+15278	Each additional 100 sq. cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	\$59.93	\$87.57



Hospital Outpatient and Ambulatory Surgical Center (ASC)

Procedure Payment^{2,3,4}

HCPCS	Description	APC	Medicare Hospital Outpatient Status Indicator ²	2017 Medicare Hospital Outpatient National Average Payment ⁴	Medicare ASC Status Indicator ³	2017 Medicare ASC National Average Payment ⁴
C5271	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq. cm; first 25 sq. cm or less wound surface area	5053	T	\$452.91	(G2)	\$244.63
+C5272	Each additional 25 sq. cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	-	N	Packaged	N1	Packaged
C5273	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq. cm; first 100 sq. cm wound surface area, or 1% of body area of infants and children	5054	T	\$1,427.16	(G2)	\$770.84
+C5274	Each additional 100 sq. cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)	-	N	N1Packaged	N1	Packaged
C5275	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq. cm; first 25 sq. cm or less wound surface area	5053	T	\$453.10	(G2)	\$244.98
+C5276	Each additional 25 sq. cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	-	N	Packaged	N1	Packaged
C5277	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq. cm; first 100 sq. cm wound surface area, or 1% of body area of infants and children	5053	T	\$452.91	(G2)	\$244.63
+C5278	Each additional 100 sq. cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)	-	N	Packaged	N1	Packaged

T: Significant procedure, multiple reduction applies

N: Items and services are packaged into payment for other services

G2 Non-office-based surgical procedure added in CY 2008 or later; payment based on OPFS relative payment weight

N1 Packaged service/item; no separate payment made

HCPCS Codes

HCPCS	HCPCS Long Description	2017 Cost Category ⁵
Q4100	Skin substitute, not otherwise specified	Low



Company Information

Acera Surgical Inc., ("Acera," St. Louis, Missouri) is a bioscience company developing and commercializing a portfolio of fully synthetic electrospun scaffolds for regenerative medical applications. Acera's products exhibit a structure similar to native extracellular matrix (ECM) and thus support rapid and effective healing. The FDA cleared Acera's first product, Cerafix® Dura Substitute, in 2016 and its second product, *Restrata® Wound Matrix*, in 2017, both via 510(k), granting commercial access to markets exceeding \$1.2B in revenue. Acera is currently raising Series A financing and seeking commercialization partners.

For additional information on Acera Surgical or the *Restrata® Wound Matrix*, please visit <http://www.acera-surgical.com>.

Current Procedural Terminology © 2016 American Medical Association, All Rights Reserved

1 CMS-1654-F – Physician Fee Schedule final rule CY2017, effective through December 31, 2017

2 Medicare Hospital Outpatient Prospective Payment System (OPPS) Status Indicators describe the payment status of procedures and devices in the hospital outpatient setting; T = Procedures subject to multiple-procedure discounting rules, N = No additional payment, payment included in line items with APCs for incidental service

3 Medicare Ambulatory Surgery Center (ASC) Status Indicators describe the payment status of procedures and devices in ASC setting; G2 = Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight, N1 = Packaged service/item; no separate payment made.

4 CMS-1656-CN, July 2017 Addenda Updates– Hospital Outpatient Prospective Payment Addendum B July 2017 Update, and Ambulatory Surgical Center Payment Systems Addendum AA July 2017 Update

5 CMS-1656-FC – CY2017 Hospital Outpatient Prospective Payment System (OPPS) Final Rule with Correction Notice

Disclaimer

THE INFORMATION PRESENTED IN THIS REIMBURSEMENT GUIDE IS INTENDED FOR INFORMATIONAL PURPOSES ONLY, AND NOTHING HEREIN IS ADVICE, LEGAL ADVICE OR A RECOMMENDATION OF ANY KIND, AND IT SHOULD NOT BE CONSIDERED AS SUCH. THE CODING AND COVERAGE INFORMATION IN THIS REIMBURSEMENT GUIDE WAS OBTAINED FROM THIRD PARTY SOURCES AND IS SUBJECT TO CHANGE WITHOUT NOTICE, INCLUDING AS A RESULT IN CHANGES IN REIMBURSEMENT LAWS, REGULATIONS, RULES, AND POLICIES. REIMBURSEMENT GUIDE CONTENT IS INFORMATIONAL ONLY, GENERAL IN NATURE, AND DOES NOT COVER ALL SITUATIONS OR ALL PAYERS' RULES OR POLICIES, AND IS NOT INTENDED TO APPLY TO ANY PARTICULAR SITUATION. THE SERVICE AND THE PRODUCT MUST BE REASONABLE AND NECESSARY FOR THE CARE OF THE PATIENT TO SUPPORT REIMBURSEMENT. PROVIDERS SHOULD REPORT THE PROCEDURE AND RELATED CODES THAT MOST ACCURATELY DESCRIBE THE PATIENT'S MEDICAL CONDITION, PROCEDURES PERFORMED, AND THE PRODUCTS USED. THE INFORMATION PRESENTED IN THIS REIMBURSEMENT GUIDE REPRESENTS NO PROMISE OR GUARANTEE FROM ACERA SURGICAL REGARDING COVERAGE OR PAYMENT FOR PRODUCTS OR PROCEDURES BY MEDICARE OR OTHER PAYERS. PROVIDERS SHOULD CHECK MEDICARE BULLETINS, MANUALS, PROGRAM MEMORANDA, AND MEDICARE GUIDELINES TO ENSURE COMPLIANCE WITH MEDICARE REQUIREMENTS. INQUIRIES CAN BE DIRECTED TO THE HOSPITAL'S MEDICARE PART A FISCAL INTERMEDIARY, THE PHYSICIAN'S MEDICARE PART B CARRIER, THE APPLICABLE MEDICARE ADMINISTRATIVE CONTRACTOR, OR TO APPROPRIATE PAYERS. ACERA SURGICAL SPECIFICALLY DISCLAIMS LIABILITY OR RESPONSIBILITY FOR THE RESULTS OR CONSEQUENCES OF ANY ACTIONS TAKEN IN RELIANCE ON INFORMATION PRESENTED IN THIS REIMBURSEMENT GUIDE. ADDITIONALLY, THE INFORMATION PROVIDED IN THIS REIMBURSEMENT GUIDE SHOULD NOT BE MISCONSTRUED AS ADVERTISING OR PROMOTION. ACERA SURGICAL NEITHER PROMOTES NOR ADVOCATES OFF-LABEL USE OF ANY ACERA SURGICAL PRODUCT. PLEASE CONSULT THE PRODUCT LITERATURE SUPPLIED WITH ACERA SURGICAL PRODUCTS TO DETERMINE INTENDED USE.