

RESTORIGIN™

Reimbursement Guide 2023

DISTRIBUTED BY:



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GENERAL REIMBURSEMENT AND CODING

Reimbursement and coverage eligibility for the use of Restorigin™ Amniotic Membrane and associated procedures varies by Medicare and Private Payors. Coverage policies, prior authorizations, contract terms, billing edits and site of service influence reimbursement.

Place of Service (POS) Codes

POS codes are 2-digit numbers included on health care professional claims to indicate the setting in which a service was provided. The Centers for Medicare and Medicaid Services (CMS) maintain POS codes used throughout the healthcare industry. Listed below are POS and descriptions that typically apply to our products. These codes should be used on professional claims to specify the entity where service(s) were rendered. Check with individual payors for reimbursement policies regarding these codes.

Place of Service Code 11 – Office

Location other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or Local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.

Place of Service Code 12 – Home

Location, other than a hospital or other facility, where the patient receives care in a private residence.

Place of Service Code 32 – Nursing Facility

A facility which primarily provides to residents skilled nursing care and related services for the rehabilitation of injured, disabled, or sick persons, or, on a regular basis, health-related care services above the level of custodial care to other than individuals with intellectual disabilities.

CPT PROCEDURE CODES AND MEDICARE PAYMENTS

Medicare has designated specific CPT codes (15271-15278) for qualified healthcare providers to report the application of skin substitute graft procedures when applying CTPs/Skin substitute products. The selection of the code is based upon the location and size of the defect.

Ensure the medical record reflects these elements and a procedure description including the fixation method.

Payment for skin substitutes can vary by Medicare contractor. Some contractors do not provide separate reimbursement for the products unless they are specifically FDA-labeled or cleared for use in the types of wounds being treated. When they are separately reimbursed, they are paid at invoice cost, as noted on the next page of this document.

CODING		PHYSICIAN OFFICE
CPT Codes	Code Description	2023 Medicare National Avg. Payment
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	\$154.57
+15272	Each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	\$24.36
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	\$315.97
+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)	\$82.96
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	\$158.69
+15276	Each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	\$32.48
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	\$345.76
+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)	\$95.78

Important Notes: The Medicare payment amounts listed do not reflect adjustments for deductible, copayments, coinsurance, sequestration or any other reductions. All payment amounts listed are based on national averages and will vary by geographical locations.

Reference: The Centers for Medicare and Medicaid Services (MPFS 01/01/2023). Retrieved from: <https://www.cms.gov/medicare/physician-fee-schedule/search>

CPT is a trademark of American Medical Association.

Restorigin™ HCPCS CODES, UPC CODES AND BILLING UNITS

Restorigin™ is billed per square centimeter. One billable unit is 1cm². To calculate the number of billable units multiply the length by the width of the piece of Restorigin™ product that was applied. The below chart lists the assigned HCPCS codes for Restorigin™ and the billable units per product size.

Restorigin™ is reimbursed by Medicare based on invoiced pricing. The billing rate is per square centimeter. Providers must check contracted payment rates for private insurers.

Preservation and Storage	SKU	UPC Code	Product Description	Size	Billing Units (per cm ²)	HCPCS Q-Code
Dehydrated Room Temp Storage	RGN-AM-0202	382567000830	Restorigin™ Amnion Patch, Thin	2x2cm	4	Q4191
	RGN-AM-0203	382567000847	Restorigin™ Amnion Patch, Thin	2x3cm	6	Q4191
	RGN-AM-0204	382567000854	Restorigin™ Amnion Patch, Thin	2x4cm	8	Q4191
	RGN-AM-0404	382567000861	Restorigin™ Amnion Patch, Thin	4x4cm	16	Q4191
	RGN-AM-0406	382567000878	Restorigin™ Amnion Patch, Thin	4x6cm	24	Q4191
	RGN-AM-0408	382567000885	Restorigin™ Amnion Patch, Thin	4x8cm	32	Q4191

Important Notes:

- The payment amounts referenced are based on 2023 Medicare national averages and do not include copayments/deductibles, sequestration, or wage index adjustments.
- Payers including some Medicare Administrative Contractors (MACs) will require the use of certain modifiers. Please check with the patient's insurance plan or MAC to identify whether modifiers are required with Q4191.
 - Common Modifiers:
 - JC – skin substitute used as a graft
 - JD – skin substitute not used as a graft
 - JW – discarded skin substitute, not used (wastage)
 - JZ – no discarded amount, single dose container

EXTREMITY CARE REIMBURSEMENT SERVICE

Reimbursement Hotline

For assistance with reimbursement questions, contact Extremity Care Reimbursement Hotline Services Monday through Friday from 9:00 am - 5:00 pm EST at 1.888.694.6694.

Extremity Care Reimbursement Hotline Services staff can assist with the following:

- Patient-specific insurance verifications
- Payer policy and Medicare Local Coverage Determination (LCD) information
- Prior authorization and pre-determination support
- General coding and reimbursement questions

To initiate insurance verification support for your patients, please submit a complete **Insurance Verification Request (IVR) Form** (see sample on page 9) with a signed practitioner authorization and **fax to 800.640.2060**. The provider is responsible for verifying individual contract or reimbursement rates with each payer. Extremity Care Reimbursement Hotline Services is not able to confirm contracted or reimbursable rates on your behalf.

SKIN SUBSTITUTE MEDICARE REIMBURSEMENT^{1,2}

Diagnosis Code Guidelines for Wound Care

Restorigin™'s coverage is based on medical necessity and subject to payer coverage guidelines. For most payers, Restorigin™ is considered medically necessary as an adjunct in the treatment of chronic wounds that fail to progress toward healing after a period of standard wound care. Providers should always follow payer coverage guidelines for covered indications.

Examples of common lower-extremity chronic wounds include:

- Diabetic foot ulcers (DFU) / diabetic ulcers of the lower extremities (ankle)
- Venous stasis ulcers (VSU) / venous leg ulcers (VLU)
- Pressure ulcers
- Chronic non-healing surgical or trauma wounds of the lower extremity with co-morbidities

ICD-10 Codes

It is recommended that providers select the most specific primary and secondary diagnosis codes to accurately describe the reason the wound is not healing properly, and codes that indicate the wound is chronic and describe the location, severity, and laterality (for lower extremity ulcers).

Refer to your local Medicare LCDs and Articles for ICD-10 coding guidance and lists of codes approved for medical necessity.

IMPORTANT BILLING INSTRUCTIONS

Restorigin™ Amniotic Membrane (Q4191) is not included on the Medicare Part B Average Sales Price (ASP) Drug Pricing File published quarterly by the Centers for Medicare and Medicaid Services (CMS).

- Average Sales Price information is published quarterly by the Centers for Medicare and Medicaid Services (CMS) in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File. Providers are encouraged to review the ASP Pricing files posted quarterly by CMS and listed by HCPCS on CMS.gov for updates.
- Payment allowance limits that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing. In determining the payment limit based on WAC, the contractors follow the methodology specified in Publication. 100-04, Chapter 17, Drugs and Biologicals, for calculating the Average Wholesale Price (AWP), but substitute WAC for AWP.
- Providers are encouraged to check with their local MACs for information on established rates
- Providers are also encouraged to check with payers to determine if an invoice is required to be submitted with the claim and/or in Box 19 of the CMS-1500 claim form.
- Providers should check with local payers regarding appropriate use of modifiers.
- Physicians should report all surgical and medical services performed, and are responsible for determining which CPT® code(s) appropriately.

DEFINITIONS

- Chronic Wounds are defined as wounds that do not respond to standard wound care treatment for at least a 30-day period of organized, comprehensive conservative therapy.
- A failed Response is defined as an ulcer or skin deficit that has failed to respond to appropriate wound-care measures, has increased in size or depth, or has not changed in baseline size or depth with no indication that improvement is likely (such as granulation, epithelialization, or progress towards closing).
- For all wounds, documentation of a comprehensive, medically necessary treatment plan is required before initiation of a specialized wound therapy product.

Medicare generally covers the application of Human Cell and Tissue Products to Ulcers or Wounds with a Failed Response that are:

- Partial-or full-thickness ulcers, not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts, with a clean granular base unless the CTP package label indicates the CTP is approved for use involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts, with a clean granular base;
- Clean and free of necrotic debris or exudate;
- Adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (ABI, toe pressure readings, etc.);
- For diabetic foot ulcers, the patient's medical record reflects a diagnosis of Type 1 or Type 2 diabetes and also reflects medical management for this condition.

DOCUMENTATION

When documenting treatment, specifically address the circumstances surrounding the wound's failure to respond to standard treatments of greater than 4 weeks. Reference specific interventions that have failed.

Clinical notes should include:

- Reason for procedure based on physical exam
- All conservative therapies previously used in the treatment of the current disease
- Specific reason why treatment is indicated for this patient
- Explanation of the planned choice of Restorigin™ Amniotic Patch
- Updated medication history
- Review of pertinent medical problems since the previous wound evaluation
- Review and documentation of procedure risks and complications
- Documentation of smoking cessation counseling and cessation measures prescribed, if applicable
- Anticipated outcomes

All documentation must be legible and maintained in the patient's record and be available to Medicare upon request. Refer to your local Medicare LCDs and Articles for specific documentation guidelines.

MODEL DOCUMENTATION FOR RESTORIGIN™ AMNIOTIC MEMBRANE


Pretreatment

- Determine medical necessity.
- Duration of ulcer: weeks
- Location of ulcer:
- Document the failed response to conservative measures.
- Establish baseline measurements of the ulcer.
- Describe the treatment of the underlying disease process contributing to the ulcer.
- Indicate the appropriate patient diagnosis codes.
- Document the status of the wound. Is it clean, free of cellulitis, infection, tunnels and tracts, eschar, or any necrotic material?
- Document if the ulcer extends through the dermis but without tendon, muscle, capsule, or bone exposure.
- Ulcer must be free of underlying osteomyelitis.
- Document conditions treated and resolved prior to start of skin substitute therapy.
 - Control of edema, venous hypertension, or lymphedema
 - Control of any nidus of infection or colonization with bacterial or fungal elements
 - Elimination of underlying cellulitis, osteomyelitis, foreign body, or malignant process
 - Appropriate debridement of necrotic tissue or foreign body (exposed bone or tendon)
 - For diabetic foot ulcers, appropriate non-weight bearing or off-loading pressure
 - For venous stasis ulcers, compression therapy provided with documented diligent use of multilayer dressings, compression stockings of greater than 20 mm Hg pressure, or pneumatic compression
 - Provision of wound environment to promote healing (protection from trauma and contaminants, elimination of inciting or aggravating processes)
- For diabetic foot ulcers, document neuropathy.
- For venous insufficiency ulcers, document venous insufficiency.
- Document the patient's blood supply (ABI, toe blood pressure readings, etc.).
- Document that the patient is competent, and/or has the support services necessary to participate in follow-on care.
- Submit IVR to Extremity Care or your Third-Party Insurance Verification Service.

During Treatment

- Document the size of the ulcer (measure width x length) immediately prior to applying Restorigin™ Amniotic Membrane: _____ sq cm
- Document if this is the initial application or a reapplication of Restorigin™ Amniotic Membrane. Refer to your local Medicare LCD for utilization parameters, such as maximum number of applications that may be used.
- Document how the graft was affixed to the patient.
- Document the name of the provider treating the patient's systemic disease and how the patient's systemic disease is being treated/monitored to ensure adequate healing of the wound site.
- Document post-application patient care.

SAMPLE IVR FORM



RESTORIGIN
Insurance Verification Request
Fax Form to 1.800.640.2060 or
email to IVR@extremitycare.com
Questions? Call: 1.888.694.6694

Required information indicated by *

New Application Additional Application
 Re-verification New Insurance

Place of Service:
 Physician Office/Clinic (POS1) Patient Home (POS12) Assisted Living Facility (POS13)
 Nursing Facility (POS32) Skilled Nursing Facility (POS31) Other

Restorigin™ Q4191
Product Requested

<input type="checkbox"/> 2x2cm	<input type="checkbox"/> 4x4cm
<input type="checkbox"/> 2x3cm	<input type="checkbox"/> 4x6cm
<input type="checkbox"/> 2x4cm	<input type="checkbox"/> 4x8cm

PATIENT AND PAYER INFORMATION

*Patient Name: _____ *DOB: _____ Male Female

Address: _____ City: _____ State: _____ Zip: _____

*Is this patient currently in a skilled nursing facility or nursing home? Yes No
 If YES, how many days has the patient been admitted to the skilled nursing facility or nursing home? _____

Primary Insurance: _____ Secondary Insurance: _____

Payer Phone #: _____ Payer Phone #: _____

Policy Number: _____ Policy Number: _____

PROVIDER AND FACILITY INFORMATION

*Provider Name: _____

*Provider ID #'s NPI: _____ Tax ID# _____ Medicare Provider # _____

*Facility Name: _____

Address: _____ City: _____ State: _____ Zip: _____

*Facility ID #'s NPI: _____ Tax ID# _____

*Facility Contact: _____ Phone#: _____ Fax#: _____

*Facility Contact Email: _____

Please fax this form along with a copy of the front and back of the patient's insurance card to 1.800.640.2060

Disclaimer: Extremity Care LLC offers insurance verification as an information service only. Information gathered during the requested research will be provided by the insurer or third-party payer. Results of this research are not a guarantee of coverage or reimbursement in the future. Extremity Care LLC disclaims liability for payment of any claims, benefits, or costs.

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FAX 1.800.640.2060

Page 1 of 1
IR-001-fm041, Revision 00

References:

- 1 www.cms.gov
- 2 This document is intended to provide information only. Use of this document and information it contains does not guarantee coverage or payment by Medicare. Providers should always choose codes that accurately describe the services provided to a patient. Providers are solely responsible for compliance with Medicare laws, rules, and requirements.
- 3 Restorigin™ pricing may be subject to a rebate, as defined in your executed fulfillment agreement.
- 4 Restorigin™ is a trademark of Parametrics Medical.
- 5 <https://www.cms.gov/medicare-coverage-database/search.aspx>

Disclaimer: This information is for educational/informational purposes only and should not be construed as authoritative. The information being presented here is current as of January 2023 and is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third-party payors is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. When making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims. Items and services that are billed to payors must be medically necessary and supported by appropriate documentation. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payor.

This information is not intended to promote the use of the product for a non-homologous use.