Coll-e-Derm™ Reimbursement Guide 2024

DISTRIBUTED BY:

ExtremityCare®

555 E North Lane, Ste 5000, Bldg D
Conshohocken, PA 19428
1.888.694.6694
customerservice@extremitycare.com

ExtremityCare®

PHONE: 1.888.694.6694
FAX: 800.640.2060

Coll-e-Derm™ is a trademark of Parametrics Medical.

Reference-0081, Revision 02

GENERAL REIMBURSEMENT AND CODING

Reimbursement and coverage eligibility for the use of Coll-e-Derm™ Acellular Dermal Matrix 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**	**2024 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	$155.68
+15272	Each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	$24.73
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	$309.80
+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)	$81.38
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	$160.39
+15276	Each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	$32.33
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	$341.73
+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)	$95.05

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 01/01/2024). Retrieved from: https://www.cms.gov/medicare/physician-fee-schedule/search

CPT is a trademark of American Medical Association.

COLL-E-DERM™ HCPCS CODES, UPC CODES AND BILLING UNITS

Coll-e-Derm™ is billed per square centimeter. One billable unit is 1cm^2. To calculate the number of billable units multiply the length by the width of the piece of Coll-e-Derm™ product that was applied. The below chart lists the assigned HCPCS codes for Coll-e-Derm™ and the billable units per product size.

Preservation and Storage	SKU	UPC Code	Product Description	Size	Billing Units (per cm^2)	HCPCS Q-Code
Hydrated Room Temp Storage	ADT22	382567000892	Coll-e-Derm™ Acellular Dermal Matrix, Thin	2x2cm	4	Q4193
	ADT23	382567000908	Coll-e-Derm™ Acellular Dermal Matrix, Thin	2x3cm	6	Q4193
	ADT24	382567000915	Coll-e-Derm™ Acellular Dermal Matrix, Thin	2x4cm	8	Q4193
	ADT44	382567000922	Coll-e-Derm™ Acellular Dermal Matrix, Thin	4x4cm	16	Q4193
	ADT46	382567000939	Coll-e-Derm™ Acellular Dermal Matrix, Thin	4x6cm	24	Q4193
	ADT48	382567000946	Coll-e-Derm™ Acellular Dermal Matrix, Thin	4x8cm	32	Q4193
	ADT22M	382567001332	Coll-e-Derm™ Acellular Dermal Matrix, Meshed	2x2cm	4	Q4193
	ADT23M	382567001233	Coll-e-Derm™ Acellular Dermal Matrix, Meshed	2x3cm	6	Q4193
	ADT24M	382567001349	Coll-e-Derm™ Acellular Dermal Matrix, Meshed	2x4cm	8	Q4193
	ADT44M	382567001356	Coll-e-Derm™ Acellular Dermal Matrix, Meshed	4x4cm	16	Q4193
	ADT46M	382567001363	Coll-e-Derm™ Acellular Dermal Matrix, Meshed	4x6cm	24	Q4193
	ADT48M	382567001370	Coll-e-Derm™ Acellular Dermal Matrix, Meshed	4x8cm	32	Q4193

Important Notes:

1. The payment amounts referenced are based on 2024 Medicare national averages and do not include copayments/deductibles, sequestration, or wage index adjustments.
2. Payors 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 Q4193.
   a. Common Modifiers:
      i. JC – skin substitute used as a graft
      ii. JD – skin substitute not used as a graft
      iii. JW – discarded skin substitute, not used (wastage)
      iv. 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;
- Payor 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 payor. 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

Coll-e-Derm™'s coverage is based on medical necessity and subject to payor coverage guidelines. For most payors, Coll-e-Derm™ 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 payor 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

Coll-e-Derm™ Acellular Dermal Matrix (Q4193) 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 payors 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 payors 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 Coll-e-Derm™ Acellular Dermal Matrix;
- 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 COLL-E-DERM™ ACELLULAR DERMAL MATRIX

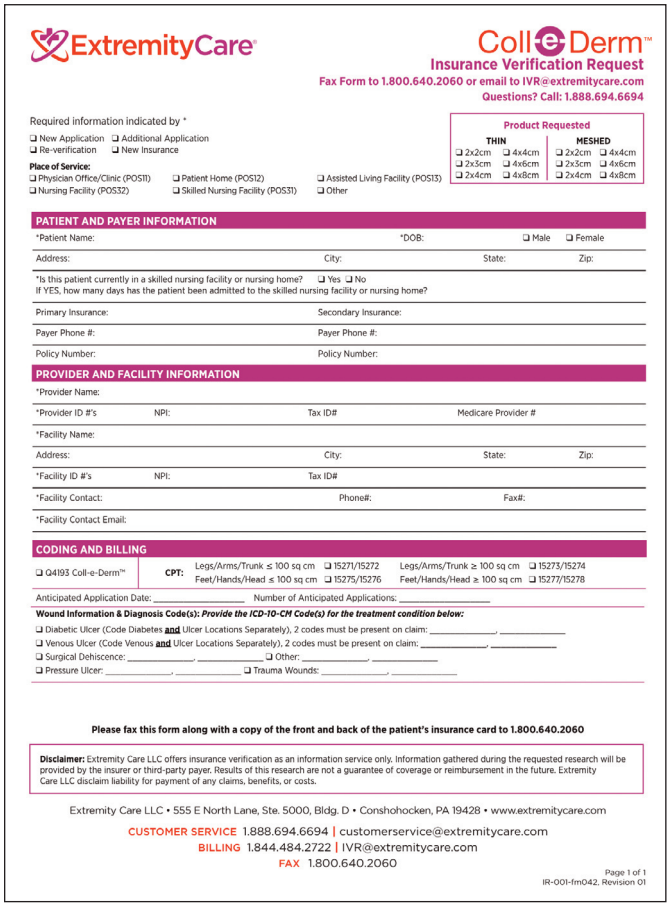
Pretreatment

1. Determine medical necessity.
2. Duration of ulcer: weeks
3. Location of ulcer.
4. Document the failed response to conservative measures.
5. Establish baseline measurements of the ulcer.
6. Describe the treatment of the underlying disease process contributing to the ulcer.
7. Indicate the appropriate patient diagnosis codes.
8. Document the status of the wound. Is it clean, free of cellulitis, infection, tunnels and tracts, eschar, or any necrotic material?
9. Document if the ulcer extends through the dermis but without tendon, muscle, capsule, or bone exposure.
10. Ulcer must be free of underlying osteomyelitis.
11. Document conditions treated and resolved prior to start of skin substitute therapy.
    a. Control of edema, venous hypertension, or lymphedema
    b. Control of any nidus of infection or colonization with bacterial or fungal elements
    c. Elimination of underlying cellulitis, osteomyelitis, foreign body, or malignant process
    d. Appropriate debridement of necrotic tissue or foreign body (exposed bone or tendon)
    e. For diabetic foot ulcers, appropriate non-weight bearing or off-loading pressure
    f. 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
    g. Provision of wound environment to promote healing (protection from trauma and contaminants, elimination of inciting or aggravating processes)
12. For diabetic foot ulcers, document neuropathy.
13. For venous insufficiency ulcers, document venous insufficiency.
14. Document the patient's blood supply (ABI, toe blood pressure readings, etc.).
15. Document that the patient is competent, and/or has the support services necessary to participate in follow-on care.
16. Submit IVR to Extremity Care or your Third-Party Insurance Verification Service.

During Treatment

1. Document the size of the ulcer (measure width x length) immediately prior to applying Coll-e-Derm™ Acellular Dermal Matrix: _____ sq cm.
2. Document if this is the initial application or a reapplication of Coll-e-Derm™ Acellular Dermal Matrix. Refer to your local Medicare LCD for utilization parameters, such as maximum number of applications that may be used.
3. Document how the graft was affixed to the patient.
4. 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.
5. Document post-application patient care.

SAMPLE IVR FORM



ExtremityCare®

Coll-e-Derm™

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 (POS11) ❑ Patient Home (POS12) ❑ Assisted Living Facility (POS13)
❑ Nursing Facility (POS32) ❑ Skilled Nursing Facility (POS31) ❑ Other

Product Requested

THIN		MESHED	
❑ 2x2cm	❑ 4x4cm	❑ 2x2cm	❑ 4x4cm
❑ 2x3cm	❑ 4x6cm	❑ 2x3cm	❑ 4x6cm
❑ 2x4cm	❑ 4x8cm	❑ 2x4cm	❑ 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:

CODING AND BILLING

❑ Q4193 Coll-e-Derm™

CPT: Legs/Arms/Trunk ≤ 100 sq cm ❑ 15271/15272 Legs/Arms/Trunk ≥ 100 sq cm ❑ 15273/15274
Feet/Hands/Head ≤ 100 sq cm ❑ 15275/15276 Feet/Hands/Head ≥ 100 sq cm ❑ 15277/15278

Anticipated Application Date: _____ Number of Anticipated Applications: _____

Wound Information & Diagnosis Code(s): *Provide the ICD-10-CM Code(s) for the treatment condition below:*

❑ Diabetic Ulcer (Code Diabetes **and** Ulcer Locations Separately), 2 codes must be present on claim: _____, _____
❑ Venous Ulcer (Code Venous **and** Ulcer Locations Separately), 2 codes must be present on claim: _____, _____
❑ Surgical Dehiscence: _____, _____ ❑ Other: _____, _____
❑ Pressure Ulcer: _____, _____ ❑ Trauma Wounds: _____, _____

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 disclaim liability for payment of any claims, benefits, or costs.

Extremity Care LLC • 555 E North Lane, Ste. 5000, Bldg. D • Conshohocken, PA 19428 • www.extremitycare.com

CUSTOMER SERVICE 1.888.694.6694 | customerservice@extremitycare.com
BILLING 1.844.484.2722 | IVR@extremitycare.com
FAX 1.800.640.2060

Page 1 of 1
IR-001-fm042, Revision 01

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 Coll-e-Derm™ pricing may be subject to a rebate, as defined in your executed fulfillment agreement.

4 Coll-e-Derm™ 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 2024 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.