

## Helicoll Billing Guide, 2025



# Helicoll

*Enhanced Collagen for Modern Wound Care*

*Information Guide*

Encoll Corporation

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## HELICOLL INFORMATION: REGULATORY & PRICING

Helicoll was originally cleared by the FDA as a medical device on August 5, 2004 with 510(k) number K040314. The product comes from USDA approved bovine sources with FDA required regulatory documentation to maintain and monitor the safety and quality of the procured animal derived raw materials.

Indications of Helicoll (US-FDA Allowed)
<ol style="list-style-type: none"> <li>1. Diabetic ulcers</li> <li>2. Pressure ulcers</li> <li>3. Venous ulcers</li> <li>4. Draining wounds</li> <li>5. Partial or full thickness wounds</li> <li>6. Tunneled, undermined wounds</li> <li>7. Surgical wounds (i.e., donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)</li> <li>8. Trauma wounds (i.e., abrasions, lacerations, second-degree burns, skin tears)</li> </ol>

### HELICOLL PRICE LIST

Federal ID (FIN): 94-3210755

National Provider ID (NPI): 1588907422

HCPCS Code: Q4164

Item Name, Size & Cat/Item #	NDC/UDI code for Billing	Pkg Type	Suggested Retail Price (SRP) (\$)	No. of units in sq. cm	SRP/Sq cm (\$)
Helicoll 0.5 in dia disc 1.27 cm dia disc (1 sq cm)	74745-0051-01	single sheet	1,560.00	1.000	1560.00
Helicoll 0.5 in dia disc 1.27 cm dia disc (1 sq cm)* Cat #HC0.5dia	74745-0052-02	2 sheets per box	3,120.00	2.000	1560.00
Helicoll 1.0 in dia disc 2.54 cm dia disc (5 sq cm)	74745-0101-01	single sheet	7,800.00	5.000	1560.00
Helicoll 1.0 in dia disc 2.54 cm dia disc (5 sq cm) Cat #HC1.0dia	74745-0102-02	2 sheets per box	15,600.00	10.000	1560.00
Helicoll 0.8 in x 1.6 in 2 cm x 4 cm (8 sq cm)	74745-0081-01	single sheet	12,480.00	8.000	1560.00
Helicoll 0.8 in x 1.6 in 2 cm x 4 cm (8 sq cm) Cat #HC0.8x1.6	74745-0082-02	2 sheets per box	24,960.00	16.000	1560.00
Helicoll 1.2 in x 1.6 in 3 cm x 4 cm (12 sq cm)	74745-0121-01	single sheet	18,720.00	12.000	1560.00
Helicoll 1.2 in x 1.6 in 3 cm x 4 cm (12 sq cm) Cat #HC1.2x1.6	74745-0122-02	2 sheets per box	37,440.00	24.000	1560.00

Helicoll 1.6 in x 1.6 in 4 cm x 4 cm (16 sq cm)	74745- 0161-01	single sheet	24,960.00	16.000	<b>1560.00</b>
Helicoll 1.6 in x 1.6 in 4 cm x 4 cm (16 sq cm) Cat #HC1.6x1.6	74745- 0162-02	2 sheets per box	49,920.00	32.000	<b>1560.00</b>
Helicoll 2 in x 2 in (25 sq cm)	74745- 0221-01	single sheet	39,000.00	25.000	<b>1560.00</b>
Helicoll 2 in x 2 in (25 sq cm) Cat #HC2x2	74745- 0225-05	5 sheets per box	195,000.00	125.000	<b>1560.00</b>
Helicoll 2 in x 4 in (50 sq cm)	74745- 0241-01	single sheet	78,000.00	50.000	<b>1560.00</b>
Helicoll 2 in x 4 in (50 sq cm) Cat #HC2x4	74745- 0245-05	5 sheets per box	390,000.00	250.000	<b>1560.00</b>

*\*Providers can verify with Medicare for rounding off the 1.27 sq cm Helicoll to its nearest next size of 2 sq cm.*  
**Complex & expensive chemical/physical processes make the price to be higher than the other products.**  
The price is subject to change without notice

# MEDICARE REIMBURSEMENT INFORMATION

(Effective January 1, 2025)

Helicoll is recognized as high-cost skin substitute. (Ref.: CMS-1809-FC Effective Date: January 1, 2025, Federal Register / Wednesday, November 27, 2024 / Rules and Regulations).

Medicare approved HCPCS CODE for Helicoll: **Q4164**

Relevant CPT Codes: **15271, 15272, 15273, 15274, 15275, 15276, 15277, and 15278**

CPT Coding: The Common Procedural Terminology (CPT®) code set describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, and payers.

Please refer the CPT descriptors below to ensure accurate billing. Determining the wound location and surface area is important in order to select the appropriate CPT code.

Add-on Codes: The + symbol signifies an add-on code. An add-on code cannot be used alone but must be billed with the initial code above it. Please check the CPT 2025 coding book for further instructions.

## Medicare Reimbursement rates for CPT 15271 to 15278

CPT Code	Differentiating code description based on			2025	
	Total wound surface area	Areas of application	Size usage at the wound surface	OPPS	ASC
15271	up to 100 sq cm	trunk, arms, legs	1 <sup>st</sup> 25 sq cm or less	\$1,829.23	\$981.09
+15272	up to 100 sq cm	trunk, arms, legs	additional 25 sq cm		
15273	≥ 100 sq cm	trunk, arms, legs	1 <sup>st</sup> 100 sq cm or 1% of body area	\$3,660.97	\$1957.33
+15274	≥ 100 sq cm	trunk, arms, legs	additional 100 sq cm		
15275	up to 100 sq cm	head, neck, hand, ft	1 <sup>st</sup> 25 sq cm or less	\$1,829.23	\$88.95
+15276	up to 100 sq cm	head, neck, hand, ft	additional 25 sq cm		
15277	≥ 100 sq cm	head, neck, hand, ft	1 <sup>st</sup> 100 sq cm or 1% of body area	\$1,829.23	\$981.09
+15278	≥ 100 sq cm	head, neck, hand, ft	additional 100 sq cm		

Medicare does not separately reimburse for most skin substitute products, including Helicoll. Therefore, when Helicoll is applied in the hospital outpatient setting, Medicare reimburses the CPT code national average payment amounts listed above; there is no separate reimbursement for skin substitutes, including Helicoll.

### Hospital Outpatient (OPPS) National Average Payment amounts <sup>1,2</sup>

CPT	OPPS Bundle Rates for 2025 without add-on codes	Helicoll Payment Rates as per Medicare
15271, 15275, 15277	\$1,829.23	Reimbursed based on the invoice amount (less applicable co-payment, 20%)
15273	\$3,660.97	

### Ambulatory Service Center (ASC) <sup>3</sup>

CPT	ASC Bundle Rates for 2025 without add-on codes
15271 & 15277	\$981.09
15275	\$88.95
15273	\$1957.33

Note: The referenced amounts above are based on the National average payment amounts listed by CMS and do not include copayments/deductible, sequestration, or wage index adjustments.

1. The CY 2025 Final Rule & Payment Rates listed separately for OPPS is available at the following link:  
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>

2. File name: January 2025 Web Addendum B.12.31.24  
<https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates>

3. File name: January\_2025\_ASC\_Addenda  
[https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11\\_Addenda\\_Updates](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates)

# PHYSICIAN SERVICES REIMBURSEMENT

(Using Part-B Claim of CMS1500 Form)

## Helicoll Product Reimbursement:

### Hospital Setting

Bill separately for services rendered at

- a. Hospital Outpatient Department (HOPD)
- b. Ambulatory Surgical Center (ASC)

### Billing Instructions:

In general, Medicare reimburses skin substitutes based on Average Sales Price (ASP) published quarterly on CMS website. Refer <https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files>

The ASP rate is per square centimeter. In the absence of ASP, the skin substitute product will be reimbursed based on Invoice or WAC/List price. Provider offices should verify with the MAC whether the product is paid for based on ASP or WAC/List or invoice price.

Based on the payment methodology, Item/Box 19 of the CMS-1500 claim form should include the NDC, product name, size & details along with the invoice amount (as seen in the purchase invoice) or the WAC/List price can be entered as found in the Red Book Database as well as in our website [www.Helicoll.com](http://www.Helicoll.com)

Red Book is a National Drug Compendia which Medicare references for drug/biological pricing (<http://micromedex.com/products/product-suites/clinical-knowledge/redbook>)

If the invoice copy is not able to be uploaded, it can be mailed and followed-up. Some MACs allow the entry of the invoiced amount in Item/Box 19 without the need for attaching a copy of the invoice while maintaining the proof of invoice for audit purposes.

If Medicare is deducting 10-20% for any Co-payment by the Patient, that amount may have to be recovered from the Additional Insurance of the Patient.

The payment for every region is covered through the respective Local MAC and such contacts are given in the link below:

<https://www.cms.gov/Medicare/Medicare-Contracting/FFSProvCustSvcGen/MAC-Website-List>

### Physician's Office Setting:

Bill for both the product as well as the procedure along with the date of service.



## MEDICARE – 2025 National Average Physician Fee Schedule

Detailed below are the national average payment amounts per CPT for the facility (when the physician treats in the hospital/ASC) or non-facility (when the physician treats in his office).

CPT	Description	National Average Payment	
		Facility (Hospital/ASC)	Non-Facility (Physician Office)
15271	Skin sub graft trunk/arm/leg	\$83.22	\$154.12
+15272	Skin sub graft trunk/arm/leg add-on	\$16.64	\$24.63
15273	Skin sub graft trunk/arm/leg child	\$193.07	\$308.24
+15274	Skin sub graft trunk/arm/leg child add-on	\$43.94	\$80.89
15275	Skin sub graft face, scalp, hands, feet, and/or multiple digits	\$92.21	\$158.78
+15276	Skin sub graft face, scalp, hands, feet, and/or multiple digits	\$24.63	\$32.29
15277	Skin sub graft face, scalp, hands, feet infants and children	\$220.03	\$340.20
+15278	Skin sub graft face, scalp, hands, feet infants and children	\$54.92	\$94.54

The actual payment may differ slightly based on the region/county. Santa Clara County Fee Schedule is given as example below (ref.: <https://www.cms.gov/medicare/physician-fee-schedule/search>).

### Carrier - San Jose-Sunnyvale-Santa Clara (Santa Clara Cnty) 0111209

CPT	Description	Adjusted Payment	
		Facility (Hospital/ASC)	Non-Facility (Physician Office)
15271	Skin sub graft trunk/arm/leg	\$95.26	\$197.00
+15272	Skin sub graft trunk/arm/leg add-on	\$18.51	\$29.98
15273	Skin sub graft trunk/arm/leg child	\$216.40	\$381.67
+15274	Skin sub graft trunk/arm/leg child add-on	\$48.39	\$101.41
15275	Skin sub graft face, scalp, hands, feet, and/or multiple digits	\$105.49	\$201.02
+15276	Skin sub graft face, scalp, hands, feet, and/or multiple digits	\$27.41	\$38.39
15277	Skin sub graft face, scalp, hands, feet infants and children	\$246.81	\$419.25
+15278	Skin sub graft face, scalp, hands, feet infants and children	\$60.91	\$117.75



## MEDICAL BILLING INFORMATION AND GUIDELINES

### HELICOLL Units Billed:

HELICOLL is intended for treatment of one patient and is utilized as single use only. Payers will reimburse for the entire one square centimeter piece; however, it is recommended that providers document wastage. **One billable unit is 1 cm<sup>2</sup>.**

The CMS-1500 form is the standard outpatient/physician office claim form used by a non-institutional provider or supplier to bill Medicare carriers <sup>4</sup>.

The UB-04 uniform billing form is the standard hospital inpatient claim form that any institutional provider can use for the billing of medical and mental health claims <sup>5</sup>.

### Modifiers

Please check with the patient's insurer or Medicare Administrative Contractor (MAC) to inquire if modifiers are required with HCPCS Q4164 and/or the CPT codes used (15271—15278). Some of the modifiers will impact reimbursement while others are informational only.

### Common modifiers <sup>5</sup> may include:

**Modifier JC:** skin substitute used as a graft

**Modifier JW:** Drug amount discarded and not administered to any patient

**Modifier JZ:** Zero drug wasted or discarded and not administered to any patient (new July 2023)

**Modifier KX:** Requirements in the medical policy have been met.

**Modifier 25:** is significant, separately identifiable evaluation and management [E/M] service by the same physician or Other Qualified Health Care Professional on the same day of the procedure or other service.

**Modifier 59:** Distinct Procedural Service

**Modifier 76:** Repeat Procedure or Service by Same Physician or Other Qualified Health Care Professional

**\*Modifiers (XE, XP, XS, XU) are used to define specific subsets of the 59 Modifier.**

**Modifier XE:** a separate encounter, a service that is distinct because it occurred during a separate encounter

**Modifier XP:** a separate practitioner, a service that is distinct because it was performed by a different practitioner

**Modifier XS:** a separate structure, a service that is distinct because it was performed on a separate organ/structure

**Modifier XU:** an unusual non-overlapping service, the use of a service that is distinct because it does not overlap usual components of the main service

**Modifier TA:** left foot, great toe HCPCS Modifier Code

**Modifier TG:** Complex/high tech level care HCPCS Modifier Code

4. <https://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/1500>

5. <https://www.verywellhealth.com/preparing-the-ub-04-form-2317061>

6. <https://www.codingahead.com/2009/08/list-of-modifiers-html/>

## BILLING REMINDERS<sup>7</sup>

**Units Billed:** Helicoll is used for single use only and should be billed accordingly as to size.

**Example:** Helicoll Q4164 (2x2 inches) is billed as 25 units.

**Wound Size/Location:** Determining the wound location and surface area is important in order to select the appropriate CPT code.

**Debridement:** Debridement is considered a component code of skin substitute CPT application codes and is not typically separately reimbursed. Many insurers have specific guidelines on debridement services.

**Product Wastage Documentation Requirements:** Any amount of wasted material should be clearly documented in the medical record. Approximate amount of product unit used and Approximate amount of product unit discarded have to be noted.

**Diagnosis Code(s) Order:** Check with the insurer to ensure diagnoses are in the proper primary and secondary order on claims forms.

**Modifiers:** Check to see if modifiers are required with HCPCS Q4164 and/or the CPT codes used. See the common modifiers listed above.

**Commercial Insurers/Contracted Rates:** Some insurers require prior authorization and predeterminations before authorizing treatment for a patient.

**Medical Necessity/Documentation:** It is recommended that the provider review clinical evidence for Helicoll with respect to appropriate diagnoses, application, frequency, etc. If there is an applicable LCD or medical policy for Helicoll, all requirement and guidelines must be met in order for the patient to be covered.

7. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26pdf.pdf>

IMPORTANT PORTION OF THE INSURANCE FORM CMS1500:

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY

Relate A-L to service line below (24E)

ICD Ind.

22. RESUBMISSION CODE

ORIGINAL REF. NO.

A. \_\_\_\_\_

B. \_\_\_\_\_

C. \_\_\_\_\_

D. \_\_\_\_\_

E. \_\_\_\_\_

F. \_\_\_\_\_

G. \_\_\_\_\_

H. \_\_\_\_\_

I. \_\_\_\_\_

J. \_\_\_\_\_

K. \_\_\_\_\_

L. \_\_\_\_\_

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE

B.

C.

D. PROCEDURES, SERVICES, OR SUPPLIES

E.

F.

G.

H.

I.

J.

	From			To			PLACE OF SERVICE	EMG	(Explain Unusual Circumstances)		DIAGNOSIS POINTER	\$ CHARGES	UNITS OR UNITS	POSIT	ID.	RENDERING
	MM	DD	YY	MM	DD	YY	SERVICE		CPT/HCPCS	MODIFIER				Family Plan	QUAL.	PROVIDER ID. #
1																NPI
2																NPI
3																NPI
4																NPI
5																NPI
6																NPI

PHYSICIAN OR SUPPLIER INFORMATION



# HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

CLAIM #: 367999  
BLUE CROSS PPO/EPO/POS  
PO BOX 60007  
Att Claim, LOS ANGELES, CA 90060

PICA <input type="checkbox"/>												PICA <input type="checkbox"/>																																																											
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA BLK (LUNG) <input checked="" type="checkbox"/> OTHER <input type="checkbox"/>												1a. INSURED'S I.D. NUMBER (For Program in Item 1) 1123421																																																											
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Doe, John												3. PATIENT'S BIRTH DATE MM DD YY 01 01 01 SEX M <input checked="" type="checkbox"/> F <input type="checkbox"/>												4. INSURED'S NAME (Last Name, First Name, Middle Initial) SAME																																															
5. PATIENT'S ADDRESS (No., Street) 1234												6. PATIENT RELATIONSHIP TO INSURED Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>												7. INSURED'S ADDRESS (No., Street) SAME																																															
CITY PASADENA STATE CA												8. RESERVED FOR NUCC USE												CITY SAME STATE SAMI																																															
ZIP CODE 91101 TELEPHONE (Include Area Code) (626) 111-2233												9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)												10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO b. AUTO ACCIDENT? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO PLACE (State) c. OTHER ACCIDENT? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO 10d. CLAIM CODES (Designated by NUCC)												11. INSURED'S POLICY GROUP OR FECA NUMBER GRP 201 a. INSURED'S DATE OF BIRTH MM DD YY 01 01 01 SEX M <input checked="" type="checkbox"/> F <input type="checkbox"/> b. OTHER CLAIM ID (Designated by NUCC) c. INSURANCE PLAN NAME OR PROGRAM NAME BC 101 d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO If yes, complete items 9, 9a, and 9d.																																			
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below. SIGNATURE ON FILE Enter the product name, size, invoice or WAC price, source as RED BOOK, NDC DATE MM/DD/YYYY												13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below. SIGNATURE ON FILE																																																											
14. DATE OF CURRENT ILLNESS, INJURY, or PRE-EXISTING CONDITION MM DD YY QUAL. DATE MM DD YY												15. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY																																																											
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. 17b. NPI												18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY																																																											
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) Helicoll 2x2 in INV or WAC \$0.00 (RED BOOK) NDC: 74745-0221-01												20. OUTSIDE LAB? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO \$ CHARGES																																																											
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. A. E11.31 B. L97.111 C. L D. E. ICD-10 Codes Enter Diagnosis code(s) G. Enter Product HCPCS Code H. I. J. K. L.												22. RESUBMISSION CODE ORIGINAL REF. NO.																																																											
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. EP907 Plan I. ID. QUAL J. RENDERING PROVIDER ID. #												23. PRIOR AUTHORIZATION NUMBER																																																											
1 01 01 21 01 01 21 11 Q4164 JC JW B 5000.00 1 EI 123456789												2 01 01 21 01 01 21 11 99214 25 A 175.00 1 NPI 1234567																																																											
3 01 01 21 01 01 21 11 15271 JC B 250.00 1 EI 123456789												4 01 01 21 01 01 21 11 15272 JC B 25.00 1 NPI 1234567																																																											
5 CPT based on size & location of the wound												6 NPI																																																											
25. FEDERAL TAX I.D. NUMBER 123456789 SSN EIN <input checked="" type="checkbox"/>												26. PATIENT'S ACCOUNT NO. DOEJOH0009-172												27. ACCEPT ASSIGNMENT? (For gov't claims, see back) <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO												28. TOTAL CHARGE \$ 5450.00												29. AMOUNT PAID \$												30. Rsvd. for NUCC Use											
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) Jack Doe, MD MM/DD/YYYY												32. SERVICE FACILITY LOCATION INFORMATION Jack Doe Medical Group 123 ABC Street San Jose CA 90801												33. BILLING PROVIDER INFO & PH # (111) 223-4444 Jack Doe Medical Group 123 ABC Street San Jose CA 90801																																															
a. NPI b. EI123456789												a. 987654321 b. EI123456789																																																											

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

Clear Form

### Diagnostic Codes Used above and their Descriptions:

#	Diagnosis Code	Description
A	R2681 (R26.81)	Unsteadiness on feet
B	I7389 (I73.89)	Other specified peripheral vascular diseases
C	L03031 (L03.031)	Cellulitis of RIGHT toe
D	M79674 (M79.674)	Pain in RIGHT Toe(s)
E	M79675 (M79.675)	Pain in LEFT Toe(s)
F	L97919 (L97.919)	Non-pressure chronic ulcer of unspecified part of RIGHT lower leg with unspecified severity
G	L97929 (L97.929)	Non-pressure chronic ulcer of unspecified part of LEFT lower leg with unspecified severity
H	L03032 (L03.032)	Cellulitis of LEFT toe

### Place of Service Codes (CMS1500 box 24b)<sup>6</sup>:

Place of Service Code(s)	Place of Service Name	Place of Service Description
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.
12	Home	Location, other than a hospital or other facility, where the patient receives care in a private residence.
13	Assisted Living Facility	Congregate residential facility with self-contained living units providing assessment of each resident's needs and on-site support 24 hours a day, 7 days a week, with the capacity to deliver or arrange for services including some health care and other services. (Effective October 1, 2003)
20	Urgent Care Facility	Location, distinct from a hospital emergency room, an office, or a clinic, whose purpose is to diagnose and treat illness or injury for unscheduled, ambulatory patients seeking immediate medical attention. (Effective January 1, 2003)
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.

6. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/Website-POS-database.pdf>

### CPT/HCPCS Codes & Descriptions:

99213: Outpatient Visit of a patient to Doctor's office

Code Range for Outpatient Visit

99211-99215: Established Patient Office or Other Outpatient Services

99202-99205: New Patient Office or Other Outpatient Services

99354-99357: Prolonged Service with Direct Patient Contact

+99417 Prolonged office or other outpatient evaluation and management service(s)

Use 99417 in conjunction with 99205, 99215

Do not report 99417 on the same date of service as 99354, 99355, 99358, 99359, 99415, 99416

Do not report 99417 for any time unit less than 15 minutes

Wound Preparation Code & Description			National Average Payment		Santa Clara Cnty 09-01112	
Code	Site of prep	Wound prep area	Facility (Hospital/ASC)	Non-Facility (Physician Office)	Facility (Hospital/ASC)	Non-Facility (Physician Office)
15002	trunk, arms, legs	1st 100 sq cm or 1% body area of infant/children	\$217.37	\$342.86	\$248.92	\$429.00
15003+	trunk, arms, legs	Additional 100 sq cm or additional 1% body area of infant/children	\$44.61	\$69.24	\$49.01	\$84.35
15004	head, neck, genitalia, hands, ft	1st 100 sq cm or 1% body area of infant/children	\$256.65	\$391.46	\$296.27	\$489.73
15005+	head, neck, genitalia, hands, ft	Additional 100 sq cm or additional 1% body area of infant/children	\$88.54	\$115.84	\$98.07	\$137.24

15271: Application of skin substitute graft to trunk, arms, legs, total wound surface area lesser than or equal to 100 sq. cm; first 25 sq. cm wound surface area.

Q4164: Helicoll per square centimeter







# SAMPLE UB-04 (CMS-1450) FORM – OUTPATIENT<sup>8</sup>

## OUTPATIENT

1 Any Hospital 123 Any Street Anytown NJ 08999		2 Any Hospital 456 Any Street Anytown NJ 08999		3a PAT. CNTRL. # 1234 3b MED. RES. # 98765 5 FE D. TAX NO. 221234567		4 TYPE OF BILL 0131	
6 PATIENT NAME Doe, John		9 PATIENT ADDRESS 1234 Main Street		7 STATEMENT COVERS PERIOD 11 03 06 11 04 06		RESERVED	
10 BIRTH DATE 03 20 1971		11 SEX M		12 DATE 11 03 06		13 ADM. TYPE 08	
14 SRC 3		15 SRC 3		16 DHR 12		17 STAT 01	
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858		859		860		861	
862		863		864		865	
866		867		868		869	
870		871		872		873	
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## Prior Authorization Request



### Instructions for Prior Authorization Request:

Requesters are encouraged to include the following data elements in all Prior Authorization (PA) requests to avoid potential delays in processing. If the provider's office submits the request, it is assumed the request is sent on behalf of the facility.

**NOTE:** Only one date of service per request.

### Initial Submission Documentation

#### **Beneficiary Information (as written on their insurance card):**

Beneficiary Name:

Beneficiary's Insurance Number:

Beneficiary Date of Birth:

#### **Provider's Office Information:**

Name of Clinic:

Clinic Address:

Physician/Practitioner's Name:

Physician/Practitioner's NPI:

Physician/Practitioner's PTAN:

#### **Requester Information:**

Requester Name:

Requester Phone Number:

Requester Address:

#### **Other Information:**

Product Name & Description: Helicoll, Bioengineered Skin Substitute

Size of the Product: 0.5 in Dia disc (1 sq cm)/ 1.0 in dia disc (5 sq cm)/ 0.8x1.6 inches (8 sq cm)/ 1.2x1.6 inches (12 sq cm) / 1.6x1.6 inches (16 sq cm) / 2x2 inches (25 sq cm) / 2x4 inches (50 sq cm)

HCPCS Code(s): Q4164

Diagnosis Code(s):

Type of Bill:

Applicable CPT Codes: 15271 to 15278

Initial or subsequent request:

If expedited request, give reason:

#### **Sending a Prior Authorization Request**

Requester have the following options for submitting PA request to Insurance:

Mail

Fax

Electronic Submission of Medical Documentation (esMD)

Insurance-approved electronic portal

**Letter of Medical Necessity**  
(Please Type on Physician's Letterhead)



Date: \_\_\_\_\_

**Insurance Company:** \_\_\_\_\_

**Address:** \_\_\_\_\_

**City, State, Zip Code:** \_\_\_\_\_

**Patient's Name:** \_\_\_\_\_

**Policy Number:** \_\_\_\_\_

**Group Number:** \_\_\_\_\_

**Date of Birth:** \_\_\_\_\_

RE: Letter of Medical Necessity for Helicoll

Dear [Insurance Contact Name]:

I am writing to notify you of my intent to treat the above-mentioned patient with Helicoll (Q4164) Skin Substitute using CPT \_\_\_\_\_ for the diagnostic ICD 10 code(s): \_\_\_\_\_, \_\_\_\_\_.

The patient history is documented in the previous treatments and noticed there is no significant improvement in the cure of the ulcer wound compared to the size of the wound first examined. The patient has not responded to conservative care and other advanced treatments which is maintained in the patient records.

It is my medical expert opinion to pursue the treatment using Helicoll. I have noticed the clinical case studies document the use of Helicoll to successfully treat chronic wounds that have not responded to the standard wound care and other advanced therapies. Helicoll can expedite the healing in shorter time with lesser number of applications. Thereby it benefits and comforts the patient which also saves the healthcare costs with lesser payment by the insurance.

I feel this request of using Helicoll is medically necessary and calls for urgent need to the patient, based on the product information provided below:

**Clinical and technical features of Helicoll** (from [www.helicoll.com](http://www.helicoll.com)):

- **High purity type-I Collagen:** Helicoll is a patented reconstituted bioactive collagen sheet, free of immunogenic proteins, lipids, and elastin.
- **Faster Healing:** Collagen phosphorylation attracts cells, regenerates tissue, and stimulates blood capillaries/granulation within 4 to 5 days. No other product shows this advantage in the clinical data.
- **Innovative Technology:** Better than intact tissue-based membranes like amnion, intestinal wall, urinary bladder, etc. which contain >15% elastin. Especially the recent reviews (see annex 1) document the alarming carcinogenic effects of elastin containing intact tissue membrane derived products.
- **Pain Control:** Helicoll is also clinically proven to reduce pain compared to other standards of care

In conclusion, we strongly believe you will agree with my medical expert opinion upon my complete and thorough review to allow for treatment with Helicoll. I welcome an opportunity to discuss this with you over the phone if necessary. Please feel free to contact me if additional information is required.

Thank you for your valuable time. I look forward to hearing from you.

Sincerely,

Physician Name

Contact Information

Required Documentation (See Annex-I)

## Annex – I

### Helicoll Technical Info:

1. Helicoll published Stanford Article (2015) [https://helicoll.com/wp-content/uploads/2024/03/Helicoll\\_published\\_Stanford\\_Article.pdf](https://helicoll.com/wp-content/uploads/2024/03/Helicoll_published_Stanford_Article.pdf)
2. Shriners Hospital Burn Ctr Galveston TX (2013) [https://helicoll.com/wp-content/uploads/2024/03/Shriners\\_Hospital\\_Burn\\_Ctr\\_Galveston\\_TX.pdf](https://helicoll.com/wp-content/uploads/2024/03/Shriners_Hospital_Burn_Ctr_Galveston_TX.pdf)
3. Helicoll Clinical & Technical Features Audio-Visual [https://helicoll.com/images/Helicoll\\_AV\\_no\\_Distributor.mp4](https://helicoll.com/images/Helicoll_AV_no_Distributor.mp4)
4. Encoll Tech Product for Electric Burn Wound <https://helicoll.com/wp-content/uploads/2024/12/Encoll-Tech-Prdt-Electric-Burn-Wound-21May2021.mp4>
5. White paper on Helicoll for Diabetic Foot Ulcers [https://helicoll.com/wp-content/uploads/2024/03/Helicoll-Diabetic\\_Ulcer\\_Usage.pdf](https://helicoll.com/wp-content/uploads/2024/03/Helicoll-Diabetic_Ulcer_Usage.pdf)
6. Helicoll for Malignant Melanoma & DFU <https://helicoll.com/wp-content/uploads/2024/12/Encoll-Melanoma-DFU-24May2021.mp4>
7. Helicoll Case Reports: <https://helicoll.com/case-reports/>

### Elastin Carcinogenicity:

Please be aware of the alarming fact about the safety concerns of using an intact tissue membrane-based regenerative matrix. They all contain 15% elastin in them which happens to be the culprit (Watch this excerpt from a Panel Discussion at the Society for Biomaterials 2021 [https://www.helicoll.com/video/Helicoll\\_SFB\\_Elastin.mp4](https://www.helicoll.com/video/Helicoll_SFB_Elastin.mp4)).

Examples of such products include intact membranes of

- a. amnion (Amniofix, Epifix, Amnioexcel, Xwrap)
- b. placenta (Grafix)
- c. umbilical cord (Cellesta Cord)
- d. pericardium (Architect from Equine)
- e. urinary bladder (Cytal from Porcine)
- f. intestinal wall (Oasis from porcine SIS) and
- g. skin (Kerecis from fish, EZ Derm from porcine, Apligraf from human)

The biological degradation of Elastin resulting in Elastomer/Elastokine fragments is proven to be carcinogenic [ref. [www.nature.com/articles/s41467-020-18794-x.pdf](http://www.nature.com/articles/s41467-020-18794-x.pdf)] and could cause various pathological conditions including emphysema, chronic obstructive pulmonary disease, atherosclerosis, metabolic syndrome, etc.

[ref. <https://www.tandfonline.com/doi/full/10.1080/10409238.2020.1768208>]. There is no successful elastin-based biomaterial available until now for tissue replacement/repair applications.

Several publications including the recent article in the Nature journal confirm the possibility of elastokines or the elastin-derived matrikines being carcinogenic.

Page 7 of this article given below is the evidence for the carcinogenicity of elastin:

*"On the other hand, various elastin-derived matrikines, such as Val-Gly-Val-Ala-Pro-Gly (VGVAPG) or Ala-Gly-Val-Pro-Gly-Leu-Gly-Val-Gly (AGVPGLGVG) promote tumor progression (Ref. 113). These ECM fragments are products of the degradation of elastin through different proteolytic enzymes (elastases) (Ref. 114) and MMPs (Ref. 115). These matrikines can, in turn, also induce MMP expression and activation, including MT1-MMP and MMP-2, which would explain their tumor-promoting properties (Ref. 116)"*

**Ref. 113.** Da Silva, J. et al. Structural characterization and pro-tumor properties of a highly conserved matrikine. *Oncotarget* 9, 17839–17857 (2018).

**Ref. 114.** Werb, Z. et al., Elastases and elastin degradation. *J. Invest. Dermatol.* 79, 154s–159s (1982).

**Ref. 115.** Mecham, R. P. et al., Elastin degradation by MMPs. *J. Biol. Chem.* 272, 18071–18076 (1997).

**Ref. 116.** Brassart, B. et al., Regulation of matrix metalloproteinase-2 (gelatinase A, MMP-2), membrane-type matrix

## Annex - II

### Minimum Pre-treatment Requirement:

1. Duration of ulcer (DFU: 3 weeks, VSU: greater than 4 weeks) \_\_\_\_\_ weeks
2. Document failure to respond to conservative measures (a failed response is defined as an ulcer that has increased in size or depth and no indication that improvement is likely e.g., epithelial in growth and progression towards closure)
3. Document measurement of the ulcer at baseline, following cessation of conservative management.
4. Describe adequate treatment of the underlying disease process contributing to the ulcer
5. Diagnosis of patient
6. Document that wound is free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels and tracts, eschar or any necrotic material
7. For DFU, document current HbA1C reading (HbA1C should not exceed 12%)
8. Document adequate arterial blood supply as evidenced by an ABI of 0.65 or greater
9. For DFU, document current HbA1C reading (it should not exceed 12%)
10. Document adequate arterial blood supply as evidenced by an ABI of 0.65 or greater

### Treatment:

11. Document measurement of ulcer (width and length or circumference and depth) immediately prior to application of Helicoll \_\_\_\_\_ sq. cm
12. Document whether this is an initial application of Helicoll or a reapplication.
13. For Helicoll reapplications, document that applications have been successful (e.g., decrease in size or depth, increase in granulation tissue)
14. Document the wound dressing changes and the standard conservative measures accompanying the wound treatment with Helicoll
15. Document how the wound site was prepared, and how Helicoll was fixated on the wound

Helicoll, biological skin substitute collagen membrane normally comes in sizes from 0.5 inch dia disc (1 sq. cm) to 2x4 inches (50 sq. cm)

# PATIENT PROGRESS REPORT



## Patient Full Name:

Date of Birth: MM/DD/YYYY

Date of Visit: MM/DD/YYYY

\_\_\_\_ (Street)

City, State Zip Code

Patient-ID Number: \_\_\_\_\_

## Facility:

Facility Name

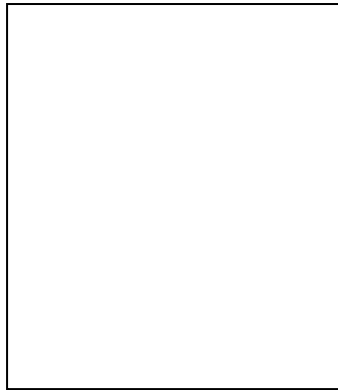
\_\_\_\_ (Street)

City, State Zip Code

Contact: \_\_\_\_\_

## Visit Summary

Ms./Mrs./Mr. \_\_\_\_\_ (Name), aged \_\_\_\_ yrs, male/female with a history of \_\_\_\_\_ (medical condition), was seen on MM/DD/YYYY for the evaluation and treatment of a \_\_\_\_\_ (health issue) on the \_\_\_\_\_ (affected body part) which is not associated with the Hospice admitting diagnosis. The patient's underlying medical conditions are managed by the facility Dr. \_\_\_\_\_ (Physician with specialty). The patient's health issue \_\_\_\_\_ (wound/ulcer) has not responded to earlier treatment(s) for the past \_\_\_\_ days by standard care of wound debridement, off-loading and other advanced wound management. The patient is scheduled for the application of Helicoll Skin Substitute to facilitate faster healing as outlined in the treatment protocol.



## Location:

\_\_\_\_\_

## Diagnosis:

1. \_\_\_\_\_

2. \_\_\_\_\_

## Classification:

\_\_\_\_\_

Width: \_\_\_\_ cm

Length: \_\_\_\_ cm

Area: \_\_\_\_ cm<sup>2</sup>

Depth: \_\_\_\_ cm

Volume: \_\_\_\_ cm<sup>2</sup>

## Product Documentation:

1. DOS: MM/DD/YYYY

2. Location: \_\_\_\_\_

3. Used product unit: \_\_\_\_ sq cm

4. Discarded product unit: \_\_\_\_ sq cm

5. Manufacturer's lot/batch # \_\_\_\_\_

## Assessment

Depth: \_\_\_\_\_

Edges: \_\_\_\_\_

Undermining: \_\_\_\_\_

Infection: \_\_\_\_\_

Edema: \_\_\_\_\_

Heat: \_\_\_\_\_

Necrotic Tissue: \_\_\_\_\_

Exudate Type: \_\_\_\_\_

Exudate Amount: \_\_\_\_\_

Peri-wound Color: \_\_\_\_\_

Erythema: \_\_\_\_\_

Granulation %: \_\_\_\_\_

Epithelialization: \_\_\_\_\_

Wound Stage: Stage \_\_\_\_\_

Odor: \_\_\_\_\_

Pain: \_\_\_\_\_

## Treatment Orders

The patient is seen on MM/DD/YYYY for the treatment of \_\_\_\_\_ (health issue) and the application of Helicoll Skin Substitute, as the \_\_\_\_ application is scheduled for today. The wound \_\_\_\_\_ (does/does not) involve tendon, muscle, joint capsule, or bone. The base of the wound is clean and ready for the application of Helicoll Skin Substitute. The wound was cleansed, debrided, and prepared for treatment. Debridement was performed down to the level of live tissue at the bottom of the wound. All slough and necrotic tissue were removed until the base of the wound was clean. Helicoll Skin substitutes was then applied onto the wound and packing of the wound was done as needed. Steri-strip was used if the edges were not adherent. There was a wastage of \_\_\_\_ sq cm of graft. A non-adherent porous dressing was then applied to the skin graft. The goal is to take the wound to 100% epithelialization or closure with Helicoll Skin Substitute. The patient tolerated the procedure well. The patient will be seen during a follow-up visit in one week for potential re-application of Helicoll Skin Substitute if needed. Detailed post procedure instructions have been provided to all caregivers.

Evaluating Staff: \_\_\_\_\_

Name: \_\_\_\_\_, WCC

Name: \_\_\_\_\_, MD

## Applicable ICD-10 Diagnosis Codes

Effective October 1, 2015, the International Classification of Diseases, 9th edition, Clinical Modification (ICD-9) code sets used to report medical diagnoses and inpatient procedures was replaced by the International Classification of Diseases, 10th edition, Clinical Modification (ICD-10). ICD-10 consists of two parts:

- ❑ ICD-10-CM diagnosis coding for use in all U.S. health care settings
- ❑ ICD-10-PCS in-patient procedure coding for use in U.S. hospital settings

ICD-10 impacts diagnosis and in-patient procedure coding for everyone covered by the Health Insurance Portability Accountability Act (HIPAA), not just those who submit Medicare or Medicaid claims. The ICD-10-CM/PCS system also provides significant improvements through greater detailed information and the ability to expand to capture additional advancements in clinical medicine. ICD-10-CM/PCS improvements include:

- Coding to higher level of specificity with proper medical documentation will result in improved ability to measure health care services
- Updated medical terminology and classification of diseases
- Increased sensitivity when refining grouping and reimbursement methodologies
- Enhanced ability to conduct public health surveillance
- Codes that allow comparison of mortality and morbidity data

ICD-10 codes must be coded to the highest level of specificity. The following table is provided for informational purposes. For specific codes to use in practice, please consult the ICD-10-CM Guidelines for Coding and Report in the AAPC 2025 ICD-10 CM coding books for additional coding guidelines. Please note that the insurer may verify and require that the diagnosis codes are in the proper order on claim forms.

ICD-10 Code	Description
<a href="#">E10.621 - E10.622</a>	Type 1 diabetes mellitus with foot ulcer - Type 1 diabetes mellitus with other skin ulcer
E11.621 - E11.622	Type 2 diabetes mellitus with foot ulcer - Type 2 diabetes mellitus with other skin ulcer
<a href="#">E13.621 - E13.622</a>	Other specified diabetes mellitus with foot ulcer - Other specified diabetes mellitus with other skin ulcer
<a href="#">I83.002 - I83.008</a>	Varicose veins of unspecified lower extremity with ulcer of calf - Varicose veins of unspecified lower extremity with ulcer other part of lower leg
I83.012 - I83.018	Varicose veins of right lower extremity with ulcer of calf - Varicose veins of right lower extremity with ulcer other part of lower leg
I83.022 - I83.028	Varicose veins of left lower extremity with ulcer of calf - Varicose veins of left lower extremity with ulcer other part of lower leg
<a href="#">I83.202 - I83.208</a>	Varicose veins of unspecified lower extremity with both ulcer of calf and inflammation - Varicose veins of unspecified lower extremity with both ulcer of other part of lower extremity and inflammation
I83.212 - I83.218	Varicose veins of right lower extremity with both ulcer of calf and inflammation - Varicose veins of right lower extremity with both ulcer of other part of lower extremity and inflammation
<a href="#">I83.222 - I83.228</a>	Varicose veins of left lower extremity with both ulcer of calf and inflammation - Varicose veins of left lower extremity with both ulcer of other part of lower extremity and inflammation
I87.311 - I87.313	Chronic venous hypertension (idiopathic) with ulcer of right lower extremity - Chronic venous hypertension (idiopathic) with ulcer of bilateral lower extremity
I87.331 - I87.333	Chronic venous hypertension (idiopathic) with ulcer and inflammation of right lower extremity - Chronic venous hypertension (idiopathic) with ulcer and inflammation of bilateral lower extremity
T87.81	Dehiscence of amputation stump

\*Always refer to the insurer-specific coverage policy or contact the insurer for instructions. The ICD-10 and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Helicoll that these codes will be appropriate or that reimbursement will be made. Coding practice will vary by site of care, patient condition, range of service provided, local payer instructions, and other factors. The decision as to how to complete a reimbursement form, including amount to bill, is exclusively the responsibility of the provider. The provider is ultimately responsible for verifying coverage with the patient's payer source.



## Applicable Medicare Severity Diagnosis Related Groups (MS-DRGs)

Diagnosis-related group (DRG) is a system which classifies hospital cases according to certain groups, also referred to as DRGs, which are expected to have similar hospital resource use (cost). There is more than one DRG system being used in the United States, but only the MS-DRG (CMS-DRG) system is used by Medicare.

MS-DRG Code	MDC	ICD-10 Med (M) /Surg (P)	Description
463	08	P	Wound debridement and skin graft except hand for musculoskeletal system and connective tissue disorders with MCC
464	08	P	Wound debridement and skin graft except hand for musculoskeletal system and connective tissue disorders with CC
465	08	P	Wound debridement and skin graft except hand for musculoskeletal system and connective tissue disorders without CC/MCC
573	09	P	Skin graft for skin ulcer or cellulitis with MCC
574	09	P	Skin graft for skin ulcer or cellulitis with CC
575	09	P	Skin graft for skin ulcer or cellulitis without CC/MCC
592	09	M	Skin ulcers with MCC
593	09	M	Skin ulcers with CC
594	09	M	Skin ulcers without CC/MCC
604	09	M	Trauma to the skin, subcutaneous tissue and breast with MCC
605	09	M	Trauma to the skin, subcutaneous tissue and breast without MCC
622	10	P	Skin grafts and wound debridement for endocrine, nutritional and metabolic disorders with MCC
623	10	P	Skin grafts and wound debridement for endocrine, nutritional and metabolic disorders with CC
624	10	P	Skin grafts and wound debridement for endocrine, nutritional and metabolic disorders without CC/MCC
904	21	P	Skin grafts for injuries with CC/MCC
905	21	P	Skin grafts for injuries without CC/MCC
927	22	P	Extensive burns or full thickness burns with MV >96 hours with skin graft
928	22	P	Full thickness burn with skin graft or inhalation injury with CC/MCC
929	22	P	Full thickness burn with skin graft or inhalation injury without CC/MCC
935	22	M	Non-extensive burns

MDC – Major Diagnostic Categories

P – Surgical

M – Medical

CC - Complication or Comorbidity

MCC - Major Complication or Comorbidity

Ref. [https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode\\_cms/P0371.html](https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/P0371.html)