Sample 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) 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.

I believe my patient will benefit from Helicoll treatment to not only expedite his/her wound healing, but reduce any extra incurred healthcare costs associated with possible adverse complications should this wound remain unhealed. I feel this request is medically urgent and necessary based on the following information concerning Helicoll.

Clinical and technical features of Helicoll (from 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://www.helicoll.com/pdf/Helicoll_published_Stanford_Article.pdf
2. Shriners Hospital Burn Ctr Galveston TX (2013) www.helicoll.com/pdf/Shriners_Hospital_Burn_Ctr_Galveston_TX.pdf
3. Helicoll Clinical & Technical Features Audio-Visual https://helicoll.com/images/Helicoll_AV_no_Distributor.mp4
4. Encoll Tech Product for Electric Burn Wound www.helicoll.com/video/Encoll_Tech_Prdt_Electric_Burn_Wound.mp4
5. White paper on Helicoll for Diabetic Foot Ulcers (Attached)
6. Helicoll for Malignant Melanoma & DFU https://www.helicoll.com/video/Encoll_Melanoma&_DFU.mp4
7. Helicoll Case Reports: https://www.helicoll.com/pdf/Helicoll_Case_Reports_2021.pdf

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 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] 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. (Helicoll is limited to 5 applications per ulcer)
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 2x2 inch (25 sq. cm) to 8x8 inches (400 sq. cm).

Durable Medical Equipment and Medical Supplies
General Prescription and Medical Necessity Review Form

Date of Delivery: (To be completed)

Section 1-5 must be completed by the DME provider. Sections. 4A, 4B, 5A, 6 and 7 must be completed by the member's prescribing provider.

Section 1-Member's Information

Member's Name & ID: (To be completed)

Address: (To be completed) Tel No. (To be completed)

Date of birth (dd/mm/yy) Gender Height Weight

ICD Code (s) _____/_____/_____/_____/_____

Diagnosis

Section 2 – Prescribing Provider's Information

Prescribing provider's name Tel No.

Address NPI

Fax No.

Section 3 – DME Provider Information

DME provider name: **Encoll Corp** Tel No. **(510) 396 8581**

Address: **4576 Enterprises St, Fremont, CA 94538** NPI: **1588907422**

Section 4 — For Durable Medical Equipment Only

Items Requested	HCPCS Code	Modifiers
1. **Helicoll**	**Q4164**	**See file attached**
2.		
3.		
4.		
5.		

Section 4A (Must be completed by prescribing provider or the prescribing provider's employee.)

Length of Need (requirements for total no. of months)

1.
2.
3.
4.
5.

Section 5 - For Durable Medical Supplies Only

Items Requested	HCPCS Code	Modifiers
1. **Helicoll**	**Q4164**	**See file attached**
2.		
3.		
4.		

Section 5A (Must be completed by prescribing provider or the prescribing provider's employee.)

Quantity monthly	Number of Refills
1.	
2.	
3.	
4.	

Section 6 –

Medical justification for requested item(s) along with any settings, therapeutic outcomes, and previous treatment plans (if applicable). Please attach any pertinent documentation (i.e., lab tests, etc.).

See sample documents attached

Section 7 — Prescribing Provider's Attestation, Signature, and Date

I certify that I am the prescribing provider identified in Section 2 of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature (Signature and date stamps are not acceptable) Date

continued ➔

Provider of DME Attestation, Signature and Date

I certify under the pains and penalties of perjury that the information on this form and any attached statement that I have provided has been reviewed and signed by me, and it is true, accurate and complete, to the best of my knowledge. I also certify that I am the provider or, in the case of a legal entity, duly authorized to act on behalf of the provider. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material contained herein. Note: Signature and date stamps, or the signature of anyone other than the provider of DME or a person legally authorized to sign on behalf of the legal entity, are not acceptable.

Provider of DME's signature: Subramanian Gunasekaran (signed)
Printed legal name of provider: Encoll Corporation (NPI: 1588907422)
Printed legal name of individual signing: Subramanian Gunasekaran

Date: _____

Instructions for Completing the Durable Medical Equipment and Medical Supplies General Prescription and Medical Necessity Review Form

(Sections 1, 2, 3, 4, and 5 must be completed by DME provider.)

Instructions for Use of this Form	DME providers should use this form when obtaining a prescription and letter of medical necessity from the member's prescribing provider for DME, and as an attachment to a prior authorization request. The DME provider is responsible for ensuring compliance with applicable regulations and requirements when completing this form. Insurance company reserves the right not to accept the form if it is completed improperly, or if the DME provider has failed to meet applicable regulations, requirements, and guidelines.
Date of Delivery	Enter the date of service.
Section 1	Enter the member's name, member ID number, home address (including apartment number if applicable), telephone number, date of birth, gender, height, weight, ICD code(s), and diagnosis that pertain to the items being dispensed.
Section 2	Enter the prescribing provider's name, telephone number, address, NPI, and fax number.
Section 3	Enter the DME provider's name, telephone number, address, NPI, and fax number.
Section 4	This section is for durable medical equipment only. Enter the description of the item(s) being supplied, the HCPCS code, and the appropriate modifier(s) being used for billing, as applicable.
Section 5	This section is for medical supplies only. Enter the description of the item(s) being supplied, the HCPCS code, and the appropriate modifier(s) being used for billing, as applicable.
Sections 4A, 5A, 6, and 7 must be completed by prescribing provider.	
Section 4A, 5A	Enter the length of need (in months).
Section 5A	Enter the monthly quantity and the number of refills (in months).
Section 6	Enter the medical justification for all items listed above. Include (if applicable) settings, therapeutic outcomes, a nd previous treatment plans. Attach any applicable supporting medical documentation (i.e., lab tests, etc.).
Section 7	The prescribing physician, nurse practitioner, or physician assistant, as appropriate, must sign and date the form. By signing the form, the prescribing provider is making the certifications contained above the signature line.