

Response to Comments: Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

A59824

Response To Comments

| Number | Comment | Response |
|--------|---|--|
| 34 | <p>A comment was received from a provider who has used the product Helicoll with success in treating a variety of wounds. They state the product has helped patient wounds heal more quickly.</p> <p>The commenter relayed that they have found that patients suffering with long-term wounds saw improved healing after treatment with this product. No literature was submitted with the comment.</p> | <p>Thank you for your comments. Medicare Administrative Contractors are required to base their coverage determinations on scientific evidence. The coverage decisions for this LCD were made based on the best evidence available at the time. No literature was submitted. If there is peer-reviewed published literature to demonstrate the product is effective, safe, and improves outcomes, it can be considered for coverage via the LCD Reconsideration process. The LCD provides a summary of evidence and analysis of evidence to support coverage decisions.</p> |

Public Versions

| Updated On | Effective Dates | Status |  |
|------------|------------------|------------------|---|
| 11/08/2024 | 01/01/2026 - N/A | Future Effective | You are here |

1. Purified Type I Collagen Wound Matrix Improves Chronic Wound Healing in Patients with Recessive Dystrophic Epidermolysis Bullosa

<https://pubmed.ncbi.nlm.nih.gov/25557742/>

<https://onlinelibrary.wiley.com/doi/10.1111/pde.12492>

2. A Clinical Study Comparing Helicoll with Scarlet Red and OpSite in the Treatment of Split Thickness Skin Graft Donor Sites—A Randomized Controlled Trial

<https://pubmed.ncbi.nlm.nih.gov/26730031/>

<https://pmc.ncbi.nlm.nih.gov/articles/PMC4692922/>

3. Healicoll: An Alternate to Flap Cover for Bare Bones and Tendons

https://journals.lww.com/amit/fulltext/2016/03010/healicoll_an_alternate_to_flap_cover_for_bare.29.aspx

Moreover, Helicoll's equivalent product has been clinically proven to show significant results with respect to haemostasis, pain relief, epithelialization and granulation tissue formation in Oral Mucosal Defects study given below. Based on this, the product was used to treat the wound following surgical excision of cancer to achieve faster tissue regeneration.

4. Evaluation of Bovine-Derived Collagen Membrane in Oral Surgical Mucosal Defects

<https://pmc.ncbi.nlm.nih.gov/articles/PMC6639437/>

5. Comparing the Efficacy of a Unique Advanced Bioengineered Type-I Collagen-Based Skin Substitute Versus an Amnion Graft With Standard of Care in the Treatment of Non-healing Diabetic Foot Ulcers: A Randomized Clinical Trial

<https://clinicaltrials.gov/study/NCT06557122?term=NCT06557122&rank=1>
<https://pmc.ncbi.nlm.nih.gov/articles/PMC11769781/>

6. A Randomized Controlled Clinical Trial Comparing the Use of High Purity Type-I Collagen-Based Skin Substitute vs. Dehydrated Human Amnion/Chorion Membrane in the Treatment of Diabetic Foot Ulcers

<https://clinicaltrials.gov/study/NCT06470087?term=NCT06470087&rank=1>
<https://pmc.ncbi.nlm.nih.gov/articles/PMC11621241/>

7. Clinical Efficacy of Type I Collagen Skin Substitutes Versus Human Amnion/Chorion in Treating Diabetic Foot Ulcers Using 55 Patient Randomized Controlled Independent Two Trials, One in India and the Other in the USA

https://link.springer.com/article/10.1007/s44174-025-00275-8?utm_source=rct_congratemailt&utm_medium=email&utm_campaign=oa_20250122&utm_content=10.1007%2Fs44174-025-00275-8

Other Anecdotal clinical studies & case reports:

1. <https://helicoll.com/clinical-studies/>
2. <https://helicoll.com/case-reports/>