Comments on Novitas Proposed LCD DL35041 Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

Presented by:

Todd P. Shaffett, DNP, FNP, CWS, FACCWS, DAPWCA

President, MedCentris

Dr. Todd P. Shaffett, DNP, FNP, CWS, FACCWS, DAPWCA

- President of MedCentris, a Wound Medicine company with over 40 locations.
- Doctorate of Nursing Practice from Southeastern Louisiana University.
- Family Nurse Practitioner treating wounds for more than 22 years.

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THANK YOU NOVITAS

- We are thankful for this opportunity to provide public comments to the proposed LCD.
- We appreciate Novitas' commitment to quality treatments for wounds that affect over 7 million people in the United States.
- We understand that chronic wounds represent a $30 billion healthcare problem, surpassing congestive heart failure, and that treatments need to be as cost-effective as possible.
- Our organization provides advanced wound medicine for highly vulnerable patients in Louisiana and Mississippi who represent the highest diabetic and amputation rates in the country, especially for minorities.
- The proposed changes in this LCD have the potential to greatly impact the healing rates of this vulnerable population either positively, or negatively.

Our Focus Regarding Proposed LCD Changes

1) **Allow clinicians to use their medical judgement to switch skin substitutes based upon the patient's needs.**
2) **Allow clinicians to use their medical judgement to determine the number of skin substitute applications, as long as the wound is progressing towards closure, retaining the current max of 10 applications over 12 weeks.**
3) **Allow clinicians to use their medical judgement to continue to select skin substitutes that are currently approved and reimbursed.**

1) Allow clinicians to use their medical judgement to switch skin substitutes based upon the patient's needs

- Although wound research has not specifically examined switching products during a wound treatment course, the proposed LCD does recommend monitoring wound progress at 1 to 4 week intervals to identify whether Treatment Modification should be considered.
- Treatment Modification also appears in the General Wound Care LCD (L35125).
- We feel strongly that Treatment Modification should include the ability to switch skin substitutes if the wound bed has changed and might benefit from a different skin substitute's composition (such as growth factor concentration or extracellular matrix thickness) as the wound evolves through the healing cycle.
- The medical judgement of the clinician treating each individual wound should be prioritized as to which skin substitute is the most appropriate at any given time.

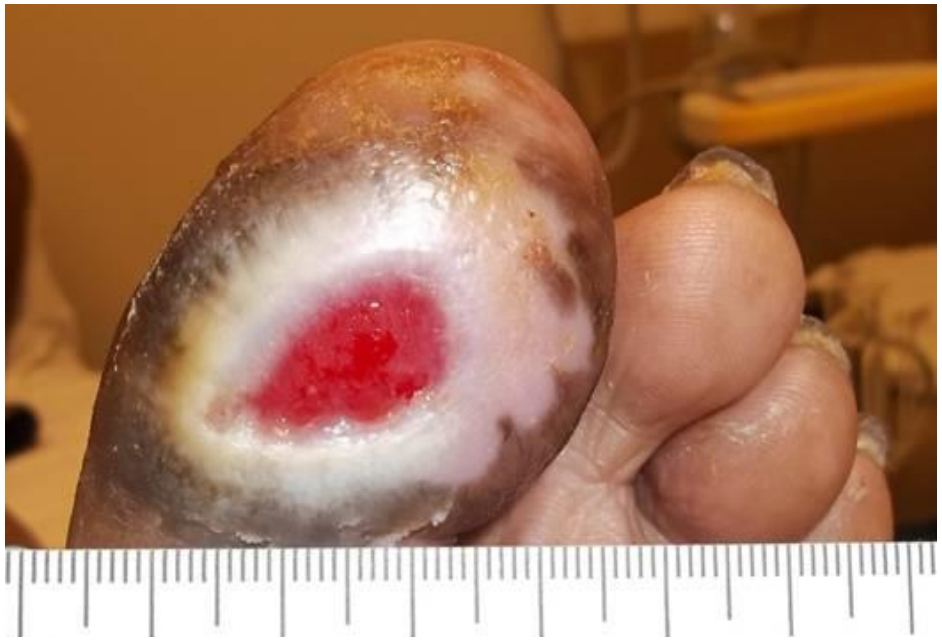
2) Allow clinicians to use their medical judgement to determine the number of skin substitute applications, as long as the wound is progressing towards closure, retaining the current max of 10 applications over 12 weeks.

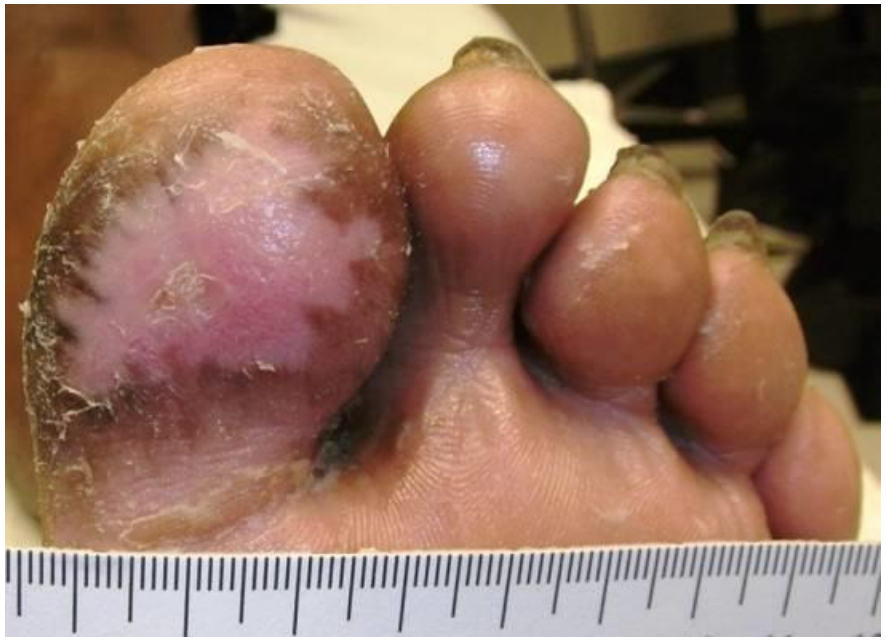
- We agree that every patient should not need the current maximum number of 10 skin substitutes to heal their wound.
- Wound healing is multifactorial, thus the number of skin substitutes indicated for each patient will vary
- Smaller wounds often require fewer skin substitutes, while larger wounds often require more skin substitutes.
- Patients with larger wounds should not be discriminated against by being denied healing modalities that could benefit them.
- The number of skin sub applications should be based on the individual factors affecting the progress of wound healing and the clinician’s medical judgement.

Continued:

- There is no literature or evidence that supports a limit of two skin substitute applications, including the references cited in the LCD.
- The studies referenced in the proposed LCD often excluded patients that received more than 2 applications.
- Studies cited by the LCD only included wounds less than 25 sq cm
- Wounds greater than 25 sq cm were excluded
- A direct correlation cannot be made that only 2 applications will have positive healing rates for all patients, wound sizes, and types.

How Many Applications To Heal This Diabetic Foot Ulcer (DFU)?





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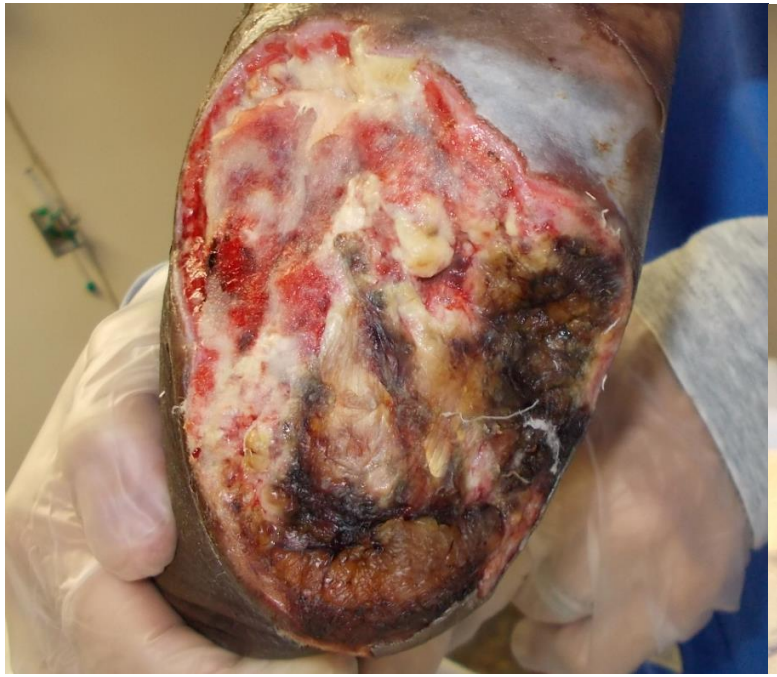
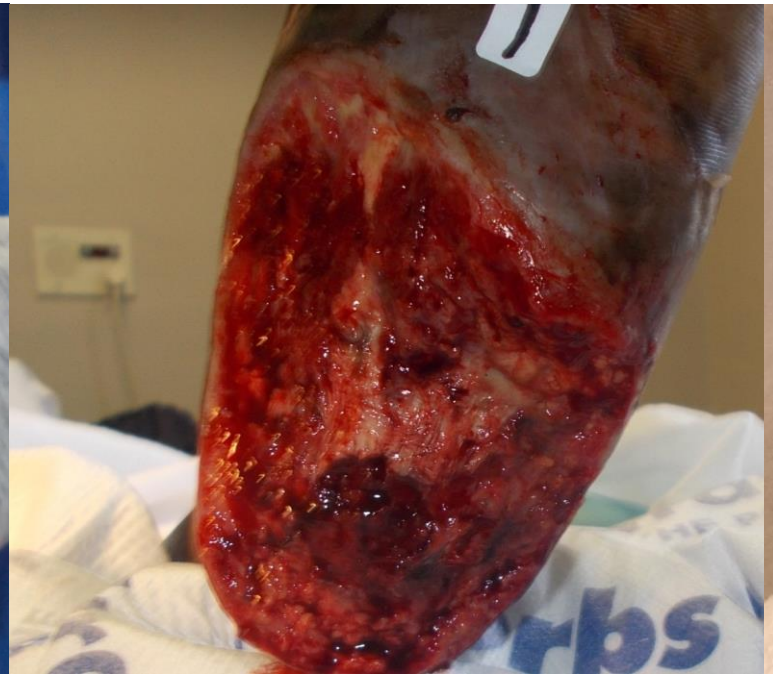
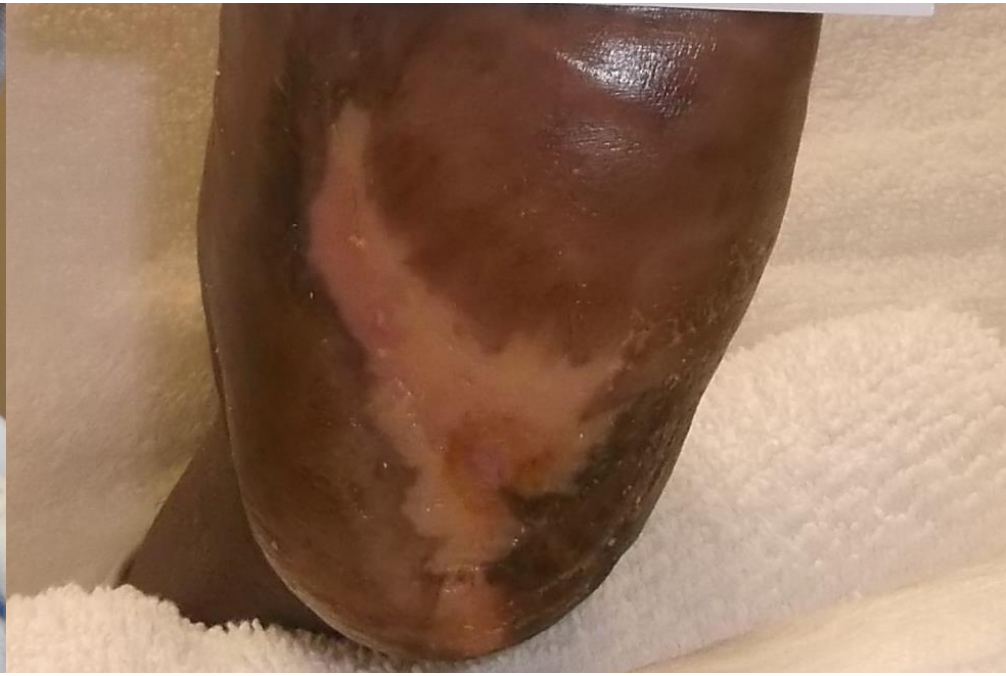
ONE

How Many Applications To Heal This DFU?







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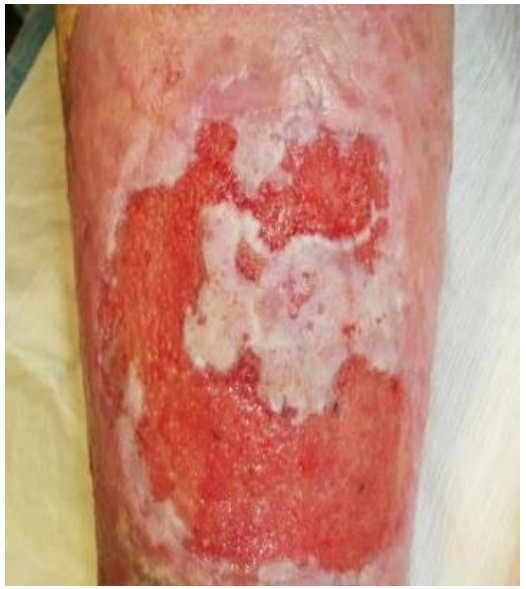
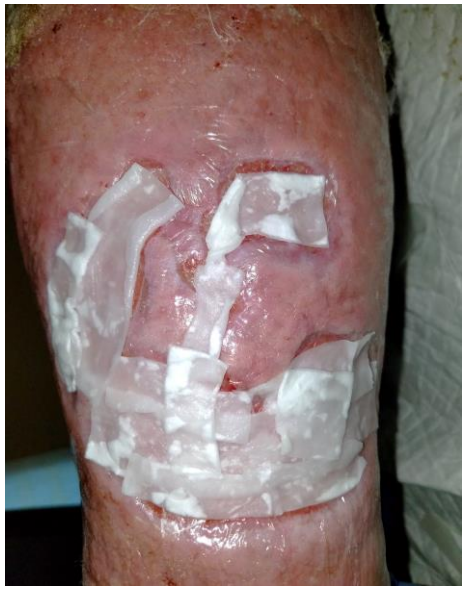
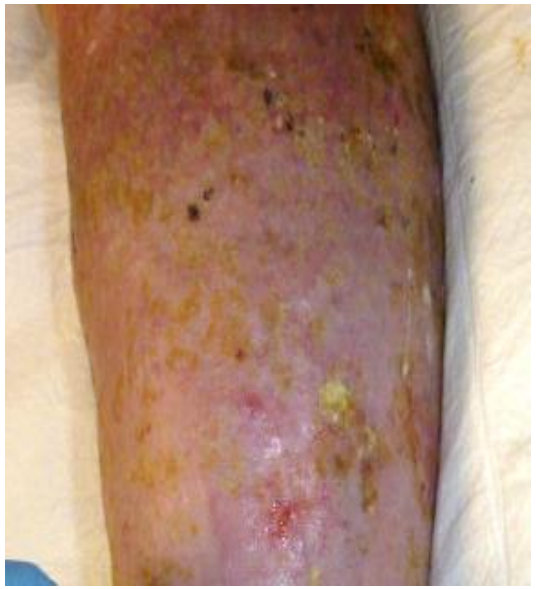
TEN

How Many Applications To Heal This VLU?







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TEN

Published evidence supports more than two applications

- The following are journal references not included in the proposed LCD, that provide evidence that more than two applications of skin substitutes are efficacious, and should be reviewed and considered before this policy is changed

Published evidence supports more than two applications, continued

- **This trial showed effectiveness up to 12 applications**

  Bianchi, C., Cazzell, S., Vayser, D., Reyzelman, A. M., Dosluoglu, H., Tovmassian, G., & EpiFix VLU Study Group. (2017). A multicenter randomized controlled trial evaluating the efficacy of dehydrated human amnion/chorion membrane (EpiFix) allograft for the treatment of venous leg ulcers. *International Wound Journal*, 114–122. https://doi.org/10.1111/iwj.12843

- **This trial showed effectiveness with a range of 6-8 applications**

  Dehghani, M., Azarpira, N., Mohammadkarimi, V., Mossayebi, H., & Esfandiari, E. (2017). Grafting with cryopreserved amniotic membrane versus conservative wound care in treatment of pressure ulcers: A randomized clinical trial. *Bulletin of Emergency and Trauma*, *5*(4), 249–258.

Preliminary Data

- We are currently conducting a non-vendor sponsored, retrospective study of skin substitute applications and associated healing rates.
- Patients that showed less than 50% area reduction at four to six weeks were included

STALLED WOUND TYPE	AVERAGE AREA REDUCTION AFTER 1ST APPLICATION	AVERAGE AREA REDUCTION AFTER 2ND APPLICATION
VENOUS LEG ULCER (n =90)	**5.56%**	**18.97%**

Preliminary Data, continued

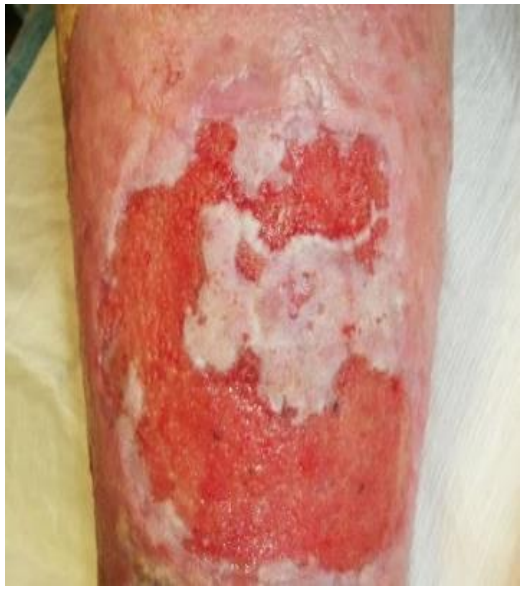
STALLED WOUND TYPE	AVERAGE AREA REDUCTION AFTER 1ST APPLICATION	AVERAGE AREA REDUCTION AFTER 2ND APPLICATION
VENOUS LEG ULCER (n =90)	**5.56%**	**18.97%**

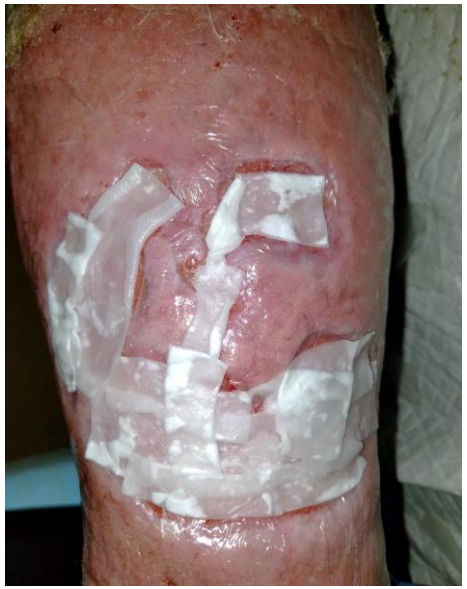
- Evidence suggests that wounds will continue to respond with continued applications of skin substitutes beyond the initial two
- Stopping skin substitute applications at two, may increase the risk of wounds stalling again and/or regressing

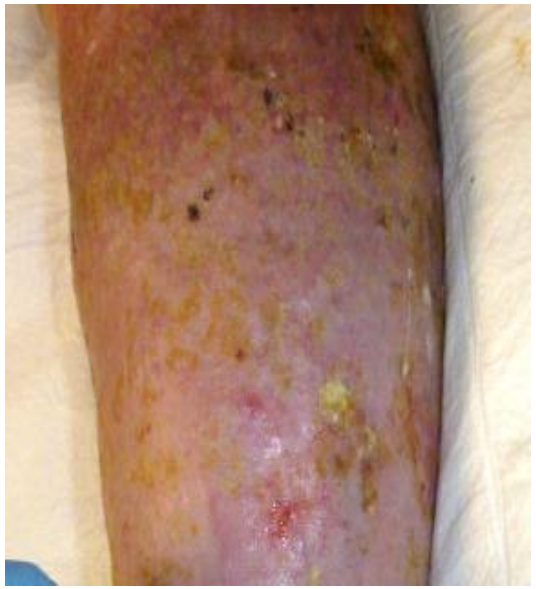
3) Allowing clinicians to use their medical judgement to continue to select grafts that are currently approved and reimbursed.

- Numerous grafts have been moved from Group 2 (covered) to Group 3 (non-covered). There doesn't seem to be a clear rationale to justify moving currently covered grafts to non-covered status.
- We have used several of the grafts that are proposed to be moved to Group 3 (non-covered), and have found many to be highly efficacious, often more so than some of the grafts that remain covered in Group 2 depending on the wound bed environment.
- We are requesting that Novitas review the list of products in Group 3 and reinstate all grafts that are currently covered back to Group 2.
- If there is a specific medical justification for the grafts in group 3 to not be covered, we respectfully request that the parameters for those decisions are disclosed publicly.

Currently Reimbursed Skin Sub







Proposed LCD: Group 3 Non-covered

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Summary

1) **Allow clinicians to use their medical judgement to switch skin substitutes based upon the patient's needs.**
2) **Allow clinicians to use their medical judgement to determine the number of skin substitute applications, as long as the wound is progressing towards closure, retaining the current max of 10 applications over 12 weeks.**
3) **Allow clinicians to use their medical judgement to continue to select skin substitutes that are currently approved and reimbursed***

**If currently reimbursed grafts are no longer to be covered, publicly provide the medical justification for the excluded skin substitutes, and the detailed process required to return them to reimbursable status.*