

## Member ALERT – Noridian Healthcare Solutions Has Limited Use of Amniotic Membrane CTPs in Jurisdictions E & F

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### Call for Evidence

Noridian Healthcare Solutions, a Medicare Administrative Contractor (MAC) just released a coverage policy Articles limiting coverage of **amniotic membrane CTPs** to only treating VLU and DFU:

This will affect the following Medicare Jurisdictions:

- Article A56155: Jurisdiction E [**CA, HI, NV**]
- Article A56156: Jurisdiction F [**AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY**]

Noridian states in the Articles: “Noridian has seen multiple claims where **amniotic membrane derived skin substitutes** are being used for indications other than the treatment of venous stasis ulcers and diabetic foot ulcers.

The original coverage of these products for VSUs and DFUs only was predicated on the fact that the literature that was available only addressed the efficacy of these products in the care of refractory VSU and DFUs. **To date we have not received any evidence based, peer reviewed clinical literature published in the core medical journals to support any other use. Therefore Noridian considers clinical use outside of the care of DSU and VSU as not reasonable and necessary and non-covered.**

Noridian will gladly review any evidence based, peer reviewed clinical literature published in the core medical journals which may indicate that coverage may be reasonable for other wound types. Such articles should include the results of robust CMS and/or FDA approved clinical trials and/or meta-analysis that support any additional indications.

Any off-label use may be reviewed manually on redetermination. The redetermination request should include medical record documentation supporting the reason for the unique usage and include full text copies of evidence based, peer reviewed articles from core medical journals supporting such use.

### Background:

Noridian currently does not have an active Local Coverage Determination (LCD) policy — it retired their policy—so the threshold for coverage had been to establish medical necessity. The MACs can use a policy Article to decrease coverage since there is no required public ‘notice and comment’ period for this action. Noridian immediately implemented this limitation without any input and has consequences:

- Clinicians had no warning of this change in coverage policy
- This may result in many claims being denied.
- Noridian and providers will be burdened with denials and appeals.
- Medicare beneficiaries may be receiving therapy now and there is no guidance or lead-time to know if current patients can continue. They may get stuck with bills when providers and hospitals are denied reimbursement.

Coverage articles such as A56155 and A56156 do not provide sufficient details to enable providers to make treatment decisions without fear of claim denials. As a result, providers may not provide medically necessary treatment with CTPs and patient care could be negatively impacted.

### What You Can Do!

1. Members living in the states impacted by these Articles need to call or send a message to the Noridian Medical Director demanding a delay in the implementation of the policy Article for at least 60 days to allow the WC community to provide evidence for use of Amniotic Membrane CTPs for other than VUs and DFUs.

#### Jurisdiction E [Article A56155]

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#### Jurisdiction F [Article A56156]

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2. If you know of evidence for other than FDU and VU indications, please email article(s) to AAWC at your earliest convenience and we will send them to Noridian.

**SEND TO: Peggy Dotson, AAWC Healthcare Public Policy Committee**  
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