

Noridian Response to Alliance letter

Ms. Nusgart,

First, thank you for corresponding with us as I hope you can provide some additional insight and assistance. Perhaps your group might be able to assimilate the evidence based, peer reviewed scientific literature published in the core medical journal(s) that would show that these products are indeed useful in the broader applications beyond DFUs and VSUs. I have requested the same from at least one supplier as well as several physicians. Anecdotal experience, while of interest, is at the bottom of acceptable evidence for determining medical necessity and reasonableness in accordance with the Social Security Act.

As for the coverage article, Noridian does have the right to restrict coverage with a coverage article. The caveat here is that each claim must be manually reviewed. While an LCD would allow an automated claims system denial, a coverage article does not. I am not aware of any automated edit and yet am aware of multiple claims specific reviews by our medical review team.

I would prefer to allow coverage once efficacy is clearly established. The main concern with anecdotal experience is that a negative experience may not be reported.

It would be a delight to have a teleconference in the near future. Not only can we further discuss this item but also a more broader reaching diatribe on the use of "skin substitutes". Today there are many and varied products that fall under this catch all at CMS for which we are striving to gather evidence for their respective uses.

Perhaps the first two weeks in 2019 would be best. Please send along several dates/times and we will shore up a mutually agreeable time.

Respectfully,

Gary

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