ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

December 14, 2018

Gary Oakes M.D.
Charles E Haley M.D., MS, FACP
Noridian LLC
900 42nd Street S
P.O Box 6781
Fargo, North Dakota 58103-6781

RE: New Local Coverage Article:
Use of Amniotic Membrane Derived Skin Substitutes (A56155) and (A56156)

Dear Drs. Haley and Oakes:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am writing in response to the coverage article published by Noridian on November 8, 2018 entitled "Use of Amniotic Membrane Derived Skin Substitutes" (A56155) and (A56156). The article stated that Noridian has determined that the clinical use of amniotic membrane derived skin substitutes outside of the care of DFU and VSU as not reasonable and necessary and non-covered. The Alliance respectfully submits that the changes set out in the article are a substantive coverage determination that requires that Noridian adhere to the requirements in the Social Security Act and CMS's manual instructions that require public notice and comment whenever a new Local Coverage Determination ("LCD") is issued. As explained below, we do not believe that Noridian has any authority to create Medicare coverage restrictions under the guise of an article that is not subject to public notice and comment. In addition, by imposing Medicare coverage restrictions without proper notice, Noridian's actions disrupt the care being provided to many Medicare beneficiaries. Therefore, we respectfully request that these coverage articles be withdrawn immediately.

The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. Our members treat patients with wounds and in doing so utilize Cellular and/or Tissue Based Products for Skin Wounds (CTPs) – which include those derived from amniotic tissue. As such we have a vested interest in this policy. A list of our members can be found at www.woundcarestakeholders.org. Our specific comments follow.

Our first concern is that the publication of a "coverage article" cannot substitute for a LCD. As you are aware, Congress has defined a LCD as "a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1395y(a)(1)(A) of this title." 42 U.S.C. §1395ff (f)(2)(B). Section 1395y(a)(1)(A) refers to the "reasonable and necessary" standard for Medicare coverage. CMS has issued

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clear instructions to Medicare contractors that develop LCDs. These are set out in Chapter 13 of the Medicare Program Integrity Manual ("Manual"). In the Manual, CMS states that a MAC "shall develop LCDs" when a MAC has "identified an item or service that is never covered under certain circumstances and wish to establish automated review in the absence of an NCD or coverage provision in an interpretive manual that supports automated review." Program Integrity Manual, § 13.4(A) (emphasis in original.) The word "shall" as used here refers to a mandatory obligation. MACs must also allow for a public notice and comment period for all new LCDs. PIM, §13.7.2.

In this case, Noridian sought to adopt a policy that amniotic membrane derived skin substitutes are not covered under Medicare because they are not reasonable and necessary. This is a substantive change because it excludes a class of skin substitutes from Medicare coverage in the states where Noridian is the Medicare Administrative Contractor. In fact, Noridian expressly stated that "Noridian considers clinical use outside of the care of DFU and VSU as not reasonable and necessary and non-covered." In addition, it is a new LCD because there is no existing Noridian LCD for skin substitutes.[1]

The Alliance respectfully submits that this action is invalid because it failed to comply with the requirements for a LCD; it attempted to exclude certain skin substitutes from Medicare coverage throughout Noridian's jurisdiction but there was no public notice and comment period as required in the Program Integrity Manual. This was not a clarification of an existing policy, as Noridian had no current LCD for amniotic membrane derived skin substitute in effect.

Moreover, labelling the action as a "coverage article" does not exempt this publication from the definition of a LCD and the procedural prerequisites for a valid LCD. There is no question that these publications were intended to establish a blanket denial of all claims for amniotic membrane derived skin substitute. In fact, it has been our experience that Medicare claims for amniotic membrane derived skin substitute have been consistently covered and paid on a claim-by-claim basis since March 2015.

Because the Social Security Act and CMS's manual instructions are unambiguous, the Alliance believes that the appropriate remedy here is to withdraw the coverage article retroactive to November 8, 2018 and to notify interested parties that they may resubmit any claims denied on the basis of the coverage article.

In addition to the procedural concerns discussed above, the Alliance is also concerned that the coverage article has had an adverse impact on the beneficiaries who are currently receiving treatment. Beneficiaries and their providers had no advance notice of the change in Medicare coverage for amniotic membrane derived skin substitutes, as would be the case with a LCD. This left providers and suppliers in a position where they were not able to prepare for the consequences of the changes made in the coverage article, and the impact on existing patient plans of care. As a result, Medicare beneficiaries who were receiving treatment using amniotic tissue were

[1]Noridian retired its Local Coverage Determination (LCD) on Skin Substitutes (L24409) in March 2014. Any non-covered products were moved to the Non-Covered Services LCD (L27445). Then in April 2015, the Non-Covered Services LCD was revised to remove the remaining non-covered skin substitute products (Q4100, Q4104, Q4105, Q4108, Q4111, Q4112, Q4113, Q4114, Q4115, Q4116, Q4117, Q4118, Q4119, Q4120, Q4122, Q4123, Q4125, Q4126, Q4127, Q4128, Q4129, Q4130, Q4132, Q4133, Q4134, Q4135, Q4136 and Q4147). Since March 2015, all cellular or tissue-based products have been covered, as medically necessary, if used in accordance with their FDA-authorized indications for use.

no longer able to continue their prescribed treatment. The Alliance submits that when CMS contractors are making policy decisions that restrict coverage, there must be advanced notice to allow providers to make preparations for patient care. Again, Noridian failed to adhere to the regulations governing the issuance of policy. Noridian was not transparent in this process, failed to appropriately issue a local coverage determination when one was warranted, and tried to circumvent the provisions of the 21st Century Cures Act.

The Alliance urges Noridian to withdraw the coverage article and instead issue a draft LCD on this issue so that the public can review and provide comments for consideration. The Alliance has worked with the MAC contractors in the past to educate medical directors and staff on many wound care issues such as in April 2018 when we provided an all-day wound care inservice to the PDAC staff and DMEMAC medical directors. Likewise, we would be pleased to have Alliance representatives from our clinical associations meet with you to discuss the appropriate use of CTPs in treating wound care patients and the evidence to support it.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director