ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

February 17, 2019

Gary Oakes, M.D.
Noridian Healthcare Solutions LLC
900 42nd Street South
P.O. Box 6781
Fargo, ND 58103-6781

Re: Local Coverage Articles A56155 and A56156
Medicare Coverage for Amniotic Membrane Derived Skin Substitutes

Dear Dr. Oakes:

Thank you for your recent email of January 22 and your gracious offer to schedule an in-person meeting during the week of March 18 to discuss Medicare coverage for amniotic membrane derived skin substitutes. We would also address the type of clinical evidence that can best describe wound care patients in the real world that are treated with cellular and/or tissue based products for skin wounds (CTPs- a more clinically accurate term than "skin substitutes".) We can certainly discuss at your convenience any other issues regarding CTPs for which you might want more information that we can provide for you at the meeting.

In addition to discussing the evidence, in order to make our meeting even more productive, we wanted to address some basic points that the Alliance of Wound Care Stakeholders ("Alliance") believes are essential to a fair and equitable resolution of this Medicare coverage issue. As stated in our previous letter of December 14, 2018 and now as explained below, the Alliance believes that Local Coverage Articles A56155 and A56156 (the "Coverage Articles") should be withdrawn. If Noridian intends to proceed with a change to Medicare coverage for amniotic membrane derived skin substitutes through the issuance of the Coverage Articles, then Noridian must comply with the formal Local Coverage Determination ("LCD") process.

A baseline issue that the Alliance believes must be resolved is the scope of a Medicare Administrative Contractor's Coverage Article. Both of the Coverage Articles state that "Noridian considers clinical use [of amniotic membrane derived skin substitutes] outside of the care of DFU and VSU as not reasonable and necessary and non-covered." This means that Noridian intends to proceed with a denial of coverage for all claims for amniotic membrane derived skin substitutes unless there is documented proof that a VLU or DFU is being treated. A Coverage Article cannot substitute for an LCD and cannot restrict Medicare coverage; therefore, the Coverage Articles need to be withdrawn.

In our previous correspondence to you, the Alliance explained that Congress has defined an 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

5225 Pooks Hill Rd | Suite 627S | Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410 | F 301.530.7946
marcia@woundcarestakeholders.org

"reasonable and necessary" standard for Medicare coverage. Neither the Medicare statute nor CMS's regulations ever mention Coverage Articles.

As you are aware, CMS has developed specific LCD procedures for a MAC to follow whenever it proposes to exclude an item or service in all cases rather than when a MAC is denying a claim on medical necessity grounds on a case-by-case basis; these LCD procedures include a formal public notice-and comment process. The most recent version of the LCD procedures is set out in Chapter 13 of the Medicare Program Integrity Manual, which implements the revisions to the LCD process enacted by Congress in the 21st Century Cures Act; the Manual revisions took effect on September 26, 2018.[1] Most notable is that Coverage Articles are not discussed in this or any previous iteration of the Program Integrity Manual, nor is there any exception that would allow a Coverage Article to change Medicare coverage or would allow a Coverage Article to be a substitute for an LCD to deny coverage.

The distinction between informal interpretations such as Coverage Articles (that can be issued unilaterally by a MAC and do not require public notice and comment) and formal changes in Medicare coverage or reimbursement is embedded in the Medicare statute. Since 1987, Congress has set a specific standard that requires public notice and comment whenever there is any (1) "rule, requirement, or other statement of policy" that (2) "establishes or changes" (3) a "substantive legal standard" that (4) governs "payment for services". 42 U.S.C. § 1395hh(a)(2). This standard that requires notice-and-comment rulemaking in a wider range of circumstances was endorsed by the United States Court of Appeals for the District of Columbia Circuit. *Allina Health Services v. Price*, 863 F.3d 937 (D.C. Cir. 2017), *cert. granted* (No. 17-1484, Sept. 27, 2018). Although this statute contains an exception to the notice and comment process for Medicare National Coverage Determinations, the logical reason for this exception is that the NCD process (and by analogy the LCD process) already requires public notice and comment as set out in public notices and in Medicare manual provisions.

The Alliance respectfully submits that the Coverage Articles made substantive changes to reduce Medicare coverage but did not follow CMS's rules for changing coverage and are not a substitute for an LCD. They improperly attempt to achieve the same goal as an LCD because they state comprehensively that the use of amniotic membrane derived skin substitutes for treatment of any condition other than a DSU or VSU is "not reasonable and necessary and non-covered." There are no exceptions.[2] These Coverage Articles also are not a clarification of an existing policy or CMS regulation already in effect, as is the case with other Coverage Articles. Rather, the Coverage Articles created a new substantive standard for Medicare coverage

Congress and CMS have specified that when a MAC determines that throughout its jurisdiction it will not cover an item or service, the LCD process that includes public participation is *the exclusive vehicle*. Otherwise, the LCD process that includes public notice and comment could be improperly circumvented or ignored routinely, which is contrary to Congress's and CMS's intent.

---

[1] CMS, Publication 100-08, CR 10901, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R854PI.pdf.

[2] The statement in the Coverage Articles that "[a]ny off label use may be reviewed manually on redetermination" does not cure this problem. It only confirms that Noridian will deny all claims for amniotic membrane derived skin substitutes not used for DFUs or VSUs, and that the provider or supplier must then resort to the Medicare appeals process to have any prospect of obtaining coverage. There is no authorization to create such a process, and ignores the reality that publications such as Coverage Articles are commonly given great weight in any Medicare administrative appeal.

We do note that in your email of January 16 and during your webinar on February 7, you referred to an automated claims system denial as the bright line distinction between using an LCD to deny coverage and using a Coverage Article to deny coverage. You were likely referring to the sentence in the former version of Section 13.4(A) of the Program Integrity Manual that reads "[c]ontractors shall develop LCDs when they have 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." Here we must respectfully disagree.

First, this sentence has been deleted from Chapter 13 of the Program Integrity Manual so it is no longer part of the Program Integrity Manual so it is not available as a basis for taking this action. Second, even if this sentence were still available, it does not support the use of the Coverage Articles for denying coverage even if the claims were processed on a case-by-case basis.

This distinction between a categorical denial that is automated and a categorical denial that occurs through manual processing is irrelevant and has not been endorsed by CMS or Congress. The definition of an LCD in the Social Security Act quoted above makes no reference to any difference between whether the denial is the result of an automated claim edit or if the denial is based upon a manual case-by-case review if each such claim will be denied anyway. The now-superseded version of Chapter 13 of the Medicare Program Integrity Manual did not make an automated review system or system edit a prerequisite or condition for developing an LCD; that can only be done through a binding statute or regulation. Instead, there are many scenarios under Congress's definition when an LCD is required; the language in the superseded version of Chapter 13 gave an example of just one scenario. Stated plainly, Chapter 13 of the Program Integrity Manual has never affirmatively permitted Medicare contractors to use Articles as the basis for excluding items or services from Medicare coverage if claims were processed manually.

In any event, CMS deleted the example you cited when it overhauled Chapter 13 in 2018 based upon the 21st Century Cures Act and other reasons, and the current text of Chapter 13 makes no mention at all of an automated review or system edit in the context of LCDs; Section 13.1.2 of the current Manual correctly refers back to the definition in the Social Security Act. As a result, the superseded provisions of Chapter 13 has no bearing on this matter. If CMS believed that having an automated review or system edit was an indispensable key element distinguishing an LCD from other publications, then CMS would have retained that language in the Manual or sought to have Congress amend the Social Security Act.

These precedents make it quite clear that Congress intended that when CMS or a CMS contractor intends to create a rule that restricts Medicare coverage or creates a new standard that affects coverage, it must follow a public notice-and-comment process that includes evaluating the information provided by interested parties such as the Alliance and its members. The Coverage Articles did not comply with this process.

Accordingly, the Alliance proposes that, during our meeting we should discuss an appropriate means for Noridian to withdraw the Coverage Articles and to reopen and revise any claim determinations made since November 8, 2018 that denied claims based on the Coverage Articles. The Alliance is happy to work with you on this project within the bounds of the precedents discussed above.

As a first step forward after withdrawal of the Coverage Articles, the Alliance is prepared to discuss the evidence that supports the use of amniotic membrane derived skin substitutes for treating wounds other than

DFUs and VSUs as well as a more fuller discussion on the type of evidence that can best describe wound care patients in the real world.

We appreciate your help on this issue and look forward to meeting with you in March.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director