ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

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Sent electronically to policya.drafts@noridian.com and to policyb.drafts@noridian.com

RE: DRAFT Local Coverage Determination (LCD) for Application of Bioengineered Skin Substitutes: Ulcers (of Lower Extremities) (DL24273)

Dear Drs. Hecker and Mangold,

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the Noridian Administrative Services' (NAS) draft LCD, "Application of Bioengineered Skin Substitutes: Ulcers (of Lower Extremities) (DL 24273). The Alliance is a nonprofit multidisciplinary trade association of health care professional and patient organizations 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. A list of our members can be found at www.woundcarestakeholders.org.

General Comments

The Alliance recognizes the challenges and difficulties that the A/B MAC contractors such as Noridian Administrative Services are facing in managing the LCD development process with new wound care biologic products entering the marketplace. We compliment NAS for leading the way in attempting to establish a fair, balanced and accurate coverage policy and taking into account the various forms of clinical evidence on which to establish coverage for these important wound care biologic products. However, this draft policy falls short and the Alliance has significant issues with this draft policy as our specific comments will reflect.

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The Alliance members appreciate the opportunity to lend their voices to participate in both the Noridian Part A and B meetings/conference calls.

We would like to clarify one issue that arose during the Noridian Part B conference call. Dr. David Armstrong (who was speaking for himself whilst also being a member of the Alliance) was asked by Dr. Hecker if he supported coverage of Class III devices which have undergone clinical trials. Dr. Armstrong stated that he was "a neophyte with regulatory affairs" but later answered, "Yes to the generalized question about clinical studies." There was much confusion after this conference call between what many Alliance members believed Dr. Hecker asked Dr. Armstrong and what others believed Dr. Hecker asked. Many interpreted what she asked quite differently. Some believe that Dr. Hecker asked if only Class III devices would (or should) be covered and that Dr. Armstrong answered yes to that question. I did not hear the question asked that way and Dr. Armstrong's response should not be interpreted in that manner especially since he had just stated in his oral testimony that "payers should cover skin substitutes if the manufacturers provide clinical evidence in peer reviewed journals showing positive outcomes of their products."

As stated later in our specific comments, the Alliance does not believe that only Class III devices should only be covered in this policy--- as Dr. Armstrong stated in his comments above, the Alliance members believe that payers should cover these devices/products if the manufacturers provide clinical evidence in peer reviewed journals showing positive outcomes of their products without regard of how they are regulated by the FDA—Class II, III or HCT/Ps.

In addition, in the Noridian Part A meeting/conference call, there seemed to be a little bit of confusion over how the FDA classifies these devices/products. We address this generally in our comments, but would welcome the opportunity to meet with you to address this in greater detail. It is our understanding that CMS's Coverage and Analysis Group has held conference calls and provided written information to the A/B MAC medical directors on this issue last year since there were questions on this. We can reach out to them and have the information resent to you if it would be helpful.

Please note that our third issue addresses our concerns associated with the use of the term "skin substitutes" since it is not a technically accurate term and does not describe the technology that is either currently or will be in the marketplace. In addition, neither the FDA nor CMS uses the terminology "skin substitutes" to describe any of the devices/products listed in this draft LCD. Therefore, solely for the purpose of our comments, we will use the term "biologic products" in place of the term "skin substitutes." While there are many terms that we could have chosen such as the term "cellular and engineered tissue alternatives" which we used in our AHRQ technology assessment comments, we decided to use the term that appears in the title of the three A/B MACs whose format we recommend that NAS use in Issue #2. These three A/B MACs (NGS, CGS, NHIC) use the title "Biologic Products for Wound Treatment and Surgical Interventions". While this term is a better alternative than "skin substitutes", it is not perfect. Therefore, the Alliance will be submitting a recommendation to NAS for a more appropriate term that encompasses all current and future products in the near future.

The Alliance represents every clinical discipline which treats patients with wounds. Our members not only treat patients but conduct clinical research on many of the products that are contained in this draft policy. As such the Alliance would value the opportunity to meet with you before the draft policy is

finalized. While many Alliance members will also be submitting their individual written comments, the Alliance's specific comments follow.

Specific Comments

While the Alliance has many issues with this draft policy, we have five main issues that provide the greatest amount of concern to our members. We have presented them not necessarily in order of importance (or our comments on "grafts" would have been first) but in order that they appear in the draft LCD. Our format for addressing them is to state the issue, identify the language in the draft LCD, address our concerns and offer our recommendations. The issues are as follows:

Issue #1

Issue: Noridian will consider making changes to its LCD depending on the outcome of the AHRQ Technology Assessment (TA) on Skin Substitutes.

Language in Draft LCD: NAS understands as of the date of publication of this draft LCD that there is a pending Technology Assessment (TA) from the Agency for Health Care Quality (AHRQ) concerning Skin Substitutes. NAS will consider making appropriate changes to this LCD based on the conclusions of that TA.

Concerns: The Alliance is very troubled that NAS would include this statement in its draft LCD since we have significant concerns with the AHRQ TA. In addition to submitting comments, we have recently met with AHRQ staff and will be meeting with those at CMS to address our concerns. We advised AHRQ that there was a conflict between the purpose of the review (to provide information and relevant studies for CMS coding purposes) and the questions asked. We believe that these questions were also wrong in that two out of the three were in regards to FDA issues which are immaterial to coding. We also stated that the sole key question was not well answered since relevant studies were missed and reviewed studies were inappropriately assessed. We addressed the following issues in detail: problems in methodology (selection of studies, outcomes and bias assessment), the misinformation on the various regulatory pathways for these products through the FDA, the identified perceived bias inherent in the studies regarding manufacturer funding and investigator blinding. We have attached our comments to AHRQ for your review. (Attachment A)

Recommendations: We encourage NAS to carefully review our comments to AHRQ so that there is a better understanding of the serious problems associated with this TA and our resulting concerns. We would also request that if NAS decides to make any changes to this LCD based on the findings of the AHRQ technology assessment after the comment period ends, that Noridian resend the policy out for notice and comment prior to it being issued in final.

Issue #2

Issue:

The Alliance requests clarification on clinical trial literature requirements and registry comments in the draft LCD.

Language in Draft LCD By this draft, NAS is tentatively adding the use of TheraSkin® (Q4121) as a payable service. However, this draft also serves as notification that NAS is also considering instituting coverage limitations under which ONLY devices for which there exists adequate clinical trial literature to clearly support their use and their superiority to standard conservative wound care therapy will be covered. We are seeking, therefore, submission by the provider and industry communities any new literature or information on current ongoing studies or trials.

As an alternative following the close of this new comment period, in the event we receive insufficient new data on these devices and their use, NAS will consider the option of covering them ONLY when used within clinical trials or active participation in a formal Registry incorporating the reporting of services provided as well as ongoing outcomes data. This would also require the study designs and/or registry standards to be consistent with AHRQ (Agency for Healthcare Research and Quality) standards and Technical Assessment criteria.

Concerns: The draft policy is confusing since in the first sentence NAS states that Noridian tentatively is adding the use of TheraSkin but later is unclear what Noridian considers as sufficient data or clinical trial literature for TheraSkin or any new or currently existing biologic product for coverage purposes. We would also request clarity on the policy statement regarding considering instituting coverage limitations related only to TheraSkin or to all biologic products in this category.

The draft policy also states that adequate clinical trial literature to clearly support the product use and their superiority to standard conservative wound care therapy is necessary in order to be covered. However, Noridian never states or offers any guidance on what is adequate trial literature.

Finally, the next paragraph gives other circumstances under which these biologic products would be covered by NAS. We are confused about which products NAS is addressing (new ones or already covered ones) and request clarification on the circumstances under which NAS would cover these biologic products in clinical trials or in registries.

Recommendations:

NAS needs to provide the specific criteria it will use for determining coverage for any biologic product so as to guide the wound care community in their research and publication efforts. This will also allow for a more transparent process for manufacturers when submitting a biologic product for coverage.

To that end, the Alliance has written a wound care research guidance document, "Consensus Principles for Wound Care Research Obtained Using a Delphi Process," published in the May/June 2012 edition of *Wound Repair and Regeneration* 20 284-293. We also recently shared this document with AHRQ – and it was very well received. The Alliance therefore would like to recommend that NAS use the Alliance guidance document as criteria for determining the type of data required before coverage is granted. This will greatly help the wound care community as it continues to conduct research for this class of product. A copy of the journal article has been attached for your review. (Attachment 2)

We discuss in the paper:

> *"While RCTs are conducted to analyze the efficacy of treatments under controlled conditions, observational studies are designed to quantify effectiveness (the ability to elicit an effect in real world practice.) Because some wound healing phenomena may be best studied initially by qualitative, descriptive, or other designs, as opposed to RCTs, the POWER panel suggests that initial research could be based on observational studies to fulfill the requirement of effectiveness in products or devices that are modification of existing products or devices; other trials could then use RCTs to answer specific questions of efficacy." (p288)*

The Alliance believes that evidence can be established for coverage not only through RCTs but also through a combination of retrospective clinical studies, scientific evidence and expert knowledge. This approach is consistent with the widely accepted definition of evidence based medicine but also adopted by the newly created important organization Patient Centered Outcomes Research Institute (PCORI). We believe that payers should cover these biologic products if the manufacturers provide clinical evidence in peer reviewed journals showing positive outcomes of their products without regard of how they are regulated by the FDA—Class II, III or HCT/Ps.

In addition, as stated in our general comments, we recognize the challenges and difficulties that Noridian Administrative Services is facing in managing the LCD development process with new wound care devices and biologic products entering the marketplace. We recommend that NAS should consider using the clear format that is used by three other A/B MACs: CGS's **Biologic Products for Wound Treatment and Surgical Interventions**, NHIC's **Biologic Products for Wound Treatment and Surgical Interventions** and NGS's **Biologic Products for Wound Treatment and Surgical Interventions**. Each of these MACs bases its coverage policies on evidence based decision making and clearly addresses the circumstances under which they cover these products and then have policy articles for each product they cover. In addition, the formats are developed with "general indications and limitations to Medicare coverage and payment" and apply them "to all materials and services related to skin substitute/replacement." The more specific coverage information pertaining to the individual biologic products are included in the local coverage articles (LCAs). This type of format should be advantageous to NAS since the contractor would not need to revise its LCD every time it makes the decision to cover a new biological product; it could merely write a new LCA.

Issue #3

Issues: Noridian has stated that it would only cover products (other than Q4101, Q4106 or Q4121) that are specifically FDA-labeled as "skin substitutes" and for use in the types of ulcers considered in this LCD. Unfortunately, the term "skin substitute" is neither used by FDA in its classification of these biologic products nor by CMS in its coding descriptors. The FDA does not intend for its clearance/approval process to be used for coding, payment, and coverage purposes. In fact, if that were the case, one would not need the FDA/CMS parallel review process. There is a necessity to recognize that FDA and CMS use different terminology to describe these devices/products and they cannot be used interchangeably. It is our recommendation that the term "skin substitute" be eliminated and new nomenclature be adopted.

Language in Draft LCD:
Coverage will not be provided under this LCD for any wound treatment that does not meet the definition of Q4101, Q4106 or Q4121. All other such products, unless they are specifically FDA-labeled as "skin substitutes" and for use in the types of ulcers considered in this LCD, will be denied coverage under this LCD. All such products will be considered to be, at most, "biologic wound dressings." Dressings, by definition, are part of the relevant Evaluation & Management (E/M) service provided and not separately payable. Examples of products considered to fall under this distinction are: Q4100, Q4102, Q4104, Q4105, Q4107, Q4108, Q4110, Q4111, Q4112, Q4113, Q4114, Q4115, Q4116, Q4117, Q4118, Q4119, Q4120, Q4122, Q4123, Q4124, Q4125, Q4126, Q4127, Q4128, Q4129, and Q4130.

Concern: Neither the FDA nor CMS uses the terminology "skin substitutes" or "biologic wound dressing" to describe any of the devices/products listed in this draft LCD.

1. The FDA does not use the term "skin substitute" to describe any of the biologic products listed in this draft LCD

   The Alliance disagrees with the terminology that Noridian has used in its draft LCD, to state that other than products in codes Q4101, Q4106 or Q412, it would only cover products that are specifically FDA-labeled as "skin substitutes" and refer to others as "biologic wound dressings." None of these biologic products included in this draft LCD are classified by FDA as "skin substitutes." There is much confusion about the use of these terms which raises the point that FDA and CMS use different terminology to describe these biologic products and cannot be used interchangeably.

   As a preliminary matter, the draft LCD does not provide an accurate summary of FDA's classification scheme for tissue-derived wound care products/devices. FDA classifies these devices as "dressing, wound, collagen" (Class II), or "dressing, wound and burn, interactive" (Class III) and human tissue intended for homologous use (Human Cells, Tissues and Cellular and Tissue-based Products-HCT/Ps).

Notwithstanding the above, FDA's classification of a device as "dressing, wound, collagen" or "dressing, wound and burn, interactive" is not determinative of a product's status for Medicare coverage purposes; rather, eligibility for Medicare coverage depends on (a) whether a product is considered a "drug or biological" under Medicare law, and (b) whether the product otherwise meets the requirements to be covered as a drug or biological provided "incident to" a physician's service.

Medicare defines the terms "drugs" and "biologicals" as those products that:

… are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary[1]*, the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.*[2]

Several biologic products are the subject of USP monographs, including but not limited to: Small Intestinal Submucosa Wound Matrix (e.g., OASIS® Wound Matrix and OASIS® Ultra Tri-Layer Matrix), Cryopreserved Human Fibroblast-Derived Dermal Substitute (e.g., Dermagraft), and Graftskin (e.g., Apligraf). As such, such products are considered a "drug or biological" under Medicare law, notwithstanding FDA's classification of such products as a "wound dressing". In addition, some of the HCT/Ps has USP issued monographs under the heading "Human Acelluar Dermal Matrix" (e.g., Graftjacket® RTM) Therefore, insofar as such products meet the remaining "incident to" requirements, such products should be identified as covered.

2. <u>The term "skin substitute" is misleading and inaccurate to describe the biologic products that are the subject of this LCD for the following reasons:</u>

    - In addition to FDA not using this term, the CMS division that addresses HCPCS coding for these biologic products abandoned the term "skin substitute" effective in 2010 when a manufacturer requested that CMS delete this term since it was an incorrect descriptor. The manufacturer stated at the 2010 CMS HCPCS Public Meeting that that this language was wrong since allografts are mislabeled as "skin substitutes." Allografts differ in structure, tissue origin, and in some cases differ from biologic products in terms of how they are approved by the FDA (human skin for transplantation not devices). CMS thus changed the descriptors and eliminated the term "skin substitutes" from all of its Q codes for these items.

    - The products listed in this draft LCD do not substitute for skin. They provide an interactive component that stimulates the repair process in order to achieve skin closure. They cannot be removed because they interact with the body.

[1] The United States Pharmacopoeia and the National Formulary are merged into one compendium.

[2] Soc. Sec. Act § 1861(t)(1).

- Farlex's online medical dictionary defines a "Skin Substitute" as "a material used to cover wounds and burns where extensive areas of skin are missing, *to promote healing*". This again does not describe accurately these products.

3. It is inaccurate to describe these devices/products as "biologic wound dressings" since this term is neither used by CMS or FDA to describe these biologic products.

   As detailed above, neither Agency uses this terminology and will only cause confusion for Noridian to introduce a term that does not describe these device/products accurately. These are not "surgical dressings" in function or technology. Surgical dressings are intended to cover a wound, protect from contamination, and to manage the wound condition such as exudate, necrotic tissue or excess dryness. They are not interactive and are identified by CMS in the surgical dressing LCD as "A codes." On the other hand, the biologic products in this LCD are identified by CMS as "Q codes are cellular and acellular tissues or cell treatments that interact with the body to enable repair, and are not removable.

Recommendations:

NAS should recognize that the terms used by FDA for clearance purposes cannot be cross walked to those used by CMS and its contractors for coverage purposes. NAS should eliminate referring to these products as "skin substitutes" (in general) or "wound dressings" (for non-covered products). As stated in our general comments, solely for the purpose of this document, we are using the term "biologic products" in place of the term "skin substitutes." While there are many terms that we could have chosen such as the term "cellular and engineered tissue alternatives" which we used in our AHRQ technology assessment comments, we decided to use the term that appears in the title of the three A/B MACs whose format we recommend that NAS use in Issue #2. These three A/B MACs (NGS, CGS, NHIC) use the title "Biologic Products for Wound Treatment and Surgical Interventions". While this term is a better alternative than "skin substitutes", it is not perfect. Therefore, the Alliance will be submitting a recommendation to NAS for a more appropriate term that encompasses all current and future products in the near future.

We also request that Noridian re-review proposed non-covered items to determine whether they meet the Medicare standard for Part B coverage.

Issue #4

Issue: NAS's definition of graft is incorrect and if it is in the final LCD, it could prevent coverage of all products since none of these products meet Noridian's definition **that they function as a permanent replacement for the lost or damaged skin.**

Language in Draft LCD

"Graft" Definition
Noridian is aware that some controversy has arisen among the provider and manufacturing community concerning the applicability of the term "graft" in the use, coding, billing of and payment for skin substitutes and their application. We also are aware that some of these skin substitute products (or "devices") may be used as true substitutes for skin, whereas other uses could more accurately be termed "scaffolding," "in growth facilitating"("matrix"), or even simply "wound dressing. "Noridian recognizes that there is no specific CMS or CPT definition of the term "graft." Dorland's Illustrated Medical Dictionary, 31st Edition (2007), defines "graft," as

"1. any tissue or organ for implantation or transplantation; and "skin graft" as "skin transplanted to replace a lost portion of the body skin surface; it may be a full-thickness or split-thickness graft."

Taber's Cyclopedic Medical Dictionary, 20th Edition (2005) defines "graft" as

"1. Tissue transplanted or implanted in a part of the body to repair a defect…."; and
"skin graft" as: "The use of small sections of skin harvested from a donor site to repair a defect or trauma of the skin,…"These definitions partially assist in the determination of which products may be considered skin substitutes. Nonetheless, neither of the definitions is ultimately helpful in determining when the products are payable as skin substitutes since the primary distinction for Medicare coverage is whether the material (or device) is being used as a true "substitute," as opposed to a tissue-ingrowth matrix, scaffolding or dressing. The definition of skin graft and, consequently, determination of what products may function as skin substitutes has obvious impact, not only on the decision of coverage, but also on that of frequency of re-application, assuming the initial decision allowed payment. Noridian therefore has established the following language as a payment guideline.

For coverage of skin substitute products (devices) subject to Noridian's Application of Skin Substitutes LCD, a product will be considered as a graft if the product is intended:
1) at the time of application to fully replace lost tissue, and
2) to achieve closure of a wound (whether in fact it is successful is not a firm criterion upon which payment would be based)

The expectation is that the product itself will function as a permanent replacement for the lost or damaged skin.

On the other hand, if the product is intended to achieve temporary closure or coverage of the wound, or to act as a matrix or scaffolding that encourages and/or otherwise supports the ingrowth of the patient's own tissues in order to achieve permanent wound closure, we will not consider that use as a "graft." Application of products, which warrant routine and/or anticipated replacement, would be - at best - wound dressings, **not** "grafts."

Concern: NAS's definition of graft is incorrect and if it is in the final LCD, it could prevent coverage of all biologic products since none of these products meet this definition **that they function as a permanent replacement for the lost or damaged skin.**

Rationale:

None of the existing biologic products used for chronic wounds actually meets the definition of a graft as set out in the Noridian LCD document. This definition specifies that grafts must be permanently incorporated into the tissue, must not require replacement, and must act to fully replace existing skin.

1. Permanently incorporated into the tissue and must not require replacement.

   Tissue products currently on the market must either be (i) periodically replaced due to degradation/remodeling of the material in the wound or (ii) removed due to tissue incompatibility (synthetic or allograft).

2. Must act to fully replace skin.

   None of the biologic products currently on the market or in the development pipeline acts to fully replace skin. Biologic products that are incorporated into the wound via degradation and remodeling clearly do not replace skin, but instead act by enabling repair/regeneration of the patient's own skin. Cadaveric dermal allografts used for the treatment of wounds are typically covered with epidermal autografts and thus do not fully replace lost tissue. Autografts are currently the only type of graft that acts to fully replace skin.

An additional consideration is that the reliance on grafts as the *standard* to which skin substitute products should be compared is not tenable in the area of chronic wounds. Autografts are not the standard of care for these wounds in the United States because patients with chronic wounds are poor candidates for grafting due to underlying disease processes such as diabetes or venous insufficiency. A number of skin substitute products that are degraded/remodeled in chronic wounds and are replaced approximately weekly act to enable partial regeneration of the patient's own skin. Assertion that they must act as grafts is a historical and inaccurate notion that does not pertain to the field today.

Finally, there are four scientific articles which are attached that support deleting language that suggests that biologic products function as a "permanent replacement" for lost or damaged skin:

- Hu S, Kirsner RS, Falanga V, Phillips T, Eaglstein WH. Evaluation of Apligraf® persistence and basement membrane restoration in donor site wounds: a pilot study. *Wound Repair Regen*. 2006 Jul-Aug;14(4):427-33. (Attachment 3)
  - Persistence: No persistence of Apligraf® DNA was found after week 4 (p. 429)
  - Conclusion: "Apligraf® DNA persisted in a minority of patients at 4 weeks in acute partial-thickness wounds. Apligraf' s®' success in speeding healing of acute wounds appears to be

related to factors other than the persistence of donor DNA or effect on basement membrane restoration."

- Marston WA, Hanft J, Norwood P, Pollak R. The efficacy and safety of Dermagraft in improving the healing of chronic diabetic foot ulcers: results of a prospective randomized trial. *Diabetes Care*. 2003; 26:1701-1705. (Attachment 4)
    - Statement regarding degradation/remodeling of product: "Dermagraft is a bio-engineered dermal substitute that laboratory data suggest has two principal modes of action. It provides living, human dermal fibroblasts that deposit matrix proteins and facilitate angiogenesis. It also provides a preformed collagen matrix, receptors, and bound growth factors that facilitate the migration of the patients' epithelial cells that close the wound." (p1704)

- Veves A, Falanga V, Armstrong DG, Sabolinski ML. Graftskin, a human skin equivalent, is effective in the management of noninfected neuropathic diabetic foot ulcers: a prospective randomized multicenter clinical trial. *Diabetes Care*. 2001; 24:290-295. (Attachment 5)
    - Statement regarding degradation/remodeling of product: "Living human skin equivalents (HSEs), which are produced by using tissue-engineering techniques, have been successful in treating chronic wounds, such as venous ulcers. Although their precise mode of action is not known, it is believed that they act by both filling the wound with extracellular matrix and inducing the expression of growth factors and cytokines that contribute to wound healing." (p290-291)

- Falanga V, Sabolinski M. A bilayered living skin construct (APLIGRAF) accelerates complete closure of hard-to-heal venous ulcers. *Wound Repair Regen*. 1999; 7:201-207. (Attachment 6)
    - Statement regarding degradation/remodeling of product: "At this point, we still do not know whether the allogenic neonatal cells of Graftskin remain in the wound and for how long. It is likely that they are able to remain in the wound for some time, at least long enough to take over and produce the right signals and substances, or long enough to instruct the resident cells and restore their own program for proper wound healing." (p206)

Recommendation:

The Alliance strongly recommends that this section be eliminated for the above named reasons. However, if NAS chooses that it wants to move forward and include a definition of the term "graft", then we are recommending this alternative language, "The expectation is that the product enables the regeneration of lost or damaged skin." If Noridian does decide to use alternative language, we ask to work with NAS to ensure that the language is acceptable to all stakeholders.

Issue #5

Issue:

The Alliance would like to address the process and decision under which Noridian removes a product from coverage. An example in the draft LCD is the removal of coverage for OASIS® products (OASIS® Wound Matrix and OASIS® Ultra Tri-Layer Matrix).

Language in Draft LCD:

In the draft LCD and ever since June 15, 2007 the LCD states: "*Numerous comments were received urging coverage for Oasis. As noted earlier in this LCD, we reviewed the change in FDA labeling and the substantial amount of literature that has emerged in review of the use of this product.*

NAS has accepted that advice, hence the addition of the Oasis™ coverage statements.

However, in the draft LCD, Noridian states that, in addition to other biologics, it will not provide coverage for OASIS® Wound Matrix and OASIS® Ultra Tri-Layer Matrix because such products are at most non-separately payable "biologic wound dressings".

Concern:

It is critical that stakeholders such as the Alliance members have an understanding and can comment on the process under which an A/B MAC such as NAS removes biologic products once they have been covered in their LCD. In the example of OASIS® Products, we can find no transparent reason for Noridian's decision to stop coverage of these products. As such, the Alliance is not only concerned about this dangerous precedent, but we also question why Noridian decided not to cover OASIS® Wound Matrix and OASIS® Ultra Tri-Layer Matrix in this draft LCD.

Since Noridian made the decision to cover OASIS® Products in 2007, (1) nothing has changed about the law or the product, which means that OASIS® Products are still eligible for coverage as "incident to" biologics, (2) the body of published clinical evidence has grown even greater than the published evidence that Noridian found was sufficient to establish coverage for OASIS® Products in 2007, and (3) there is no new evidence published since the time of Noridian' s initial positive coverage decision which suggests that OASIS® Wound Matrix and OASIS® Ultra Tri-Layer Matrix are not reasonable and necessary for the management of Medicare patients.

Recommendations:

The Alliance would like to work with the Noridian medical directors to put in place a fair, transparent and predictable policy that will explain the circumstances under which products will cease to be covered under a LCD.

In addition, there should be a notice and comment period if Noridian decides to not cover a product. Finally, in its final LCD, Noridian should continue coverage for OASIS® Wound Matrix and OASIS® Ultra Tri-Layer Matrix for the management of partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wound (abrasions, lacerations, second-degree burns, skin tears), drainage wounds, and surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, and wound dehiscence).

This positive coverage will be consistent with the 3 LCDs (NHIC, NGS, and CGS) that have stringent clinical evidence coverage thresholds. In fact, the Alliance recommends that Noridian use the LCDs (*Biologic Products for Wound Treatments and Surgical Interventions*) and Articles (*OASIS® Wound Matrix and OASIS® Ultra Tri-Layer Matrix*) created by NHIC, NGS, and CGS as the model for the final Noridian LCD and Article.

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. We would be pleased to meet with you to discuss any of them in detail. Please contact our executive director, Marcia Nusgart (marcia@woundcarestakeholders.org) at 301-530-7846 who can help answer any questions.

Sincerely,

Thomas Serena MD, Co-Chair
Alliance of Wound Care Stakeholders

Caroline E. Fife MD, Co-Chair
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Charles Drueck, MD, Chair, Biologic Products Working Group, Alliance of Wound Care Stakeholders