ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

November 7, 2013

Novitas Solutions
Medical Policy Department
Union Trust Building
Suite 600
501 Grant Street
Pittsburgh, PA 15219

Submitted Electronically to donna.mandella@Novitas-solutions.com

RE: Draft LCD – Wound Care and Bioengineered Skin Substitutes

Dear Ms. Mandella:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to Novitas Solutions ("Novitas") draft LCDs DL32687 and DL27547, "Wound Care and Bioengineered Skin Substitutes". 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. Our members not only treat patients but conduct clinical research on many of the products that are contained in this draft policy.

GENERAL COMMENTS

The Alliance is concerned that Novitas has created a draft LCD which encompasses too many wound care related services, technologies and procedures into one policy which creates confusion with generalized statements that are always related to all of the approaches. We request that Novitas separate out the technologies and corresponding treatments into more specific policies. In the event that Novitas decides not to do this, the Alliance recommends that at the very least Novitas separate out the skin substitutes (referred to by the Alliance as "Cellular and/or Tissue Based Products for Wounds (CTPs)" as described below) in a separate LCD policy.

We also are concerned that Novitas has not included the diagnosis/procedure codes related to each technology or procedure in this LCD, thus creating confusion for providers. As such, the Alliance

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recommends that prior to finalizing this policy, Novitas provide the specific diagnosis codes related to each advanced therapy to assist providers in their selection of an appropriate treatment for the appropriate patient. These codes should be itemized per technology and not simply listed in the overall policy since products differ in their approved indications and ICD-9s that will relate to these indications for use.

Furthermore, as stated in our specific comments below, the Alliance is concerned with Novitas using the term "bioengineered 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. Instead, the Alliance recommends that Novitas adopt the term "Cellular and/or tissue based products for wounds (CTPs)" which is accurate, broad-based, and inclusive of both current and future technology. Another A/B MAC contractor – Cigna Government Services - has started to utilize this more clinically accurate terminology when referring to "skin substitutes" in its LCD. Since the Alliance recently voted positively to accept adoption of this term and one other jurisdiction is already utilizing this term, we will be using the acronym "CTPs" instead of "skin substitutes" in this document.

The following are our specific comments which are presented in the order of the draft LCD rather than in order of importance. Our format for addressing them is to state the language in the draft LCD, address our concerns and offer our recommendations. The issues are as follows:

SPECIFIC COMMENTS

DEBRIDEMENT

Language in the Policy: Under the indications section, the draft policy states**, "**Debridements of the wound(s), if indicated, must be performed judiciously and at appropriate intervals. Medicare expects that with appropriate care, wound volume or surface dimension should decrease by at least 10 percent per month or wounds will demonstrate margin advancement of no less than 1 mm/week. Medicare expects the wound-care treatment plan to be modified in the event that appropriate healing is not achieved. Medicare expects fewer than five debridements involving removal of muscle and/or bone debridements to be required for management of most wounds. Payment for prolonged, repetitive debridement services requires adequate documentation of complicating circumstances that reasonably necessitated additional services.

Concerns: The Alliance has significant issues with the wording in this section. There is no specific set clinical standard of care that supports either the statement – "that the wound should decrease by at least 10 percent per month", OR "that wounds will demonstrate a margin of advancement of no less than 1 mm/week". First, wounds will not heal 1mm/wk in the initial 30 day time frame. The wound is within the inflammatory and early proliferative phase of healing at this time frame and much of the improvement is at the biochemical and cellular level and not measurable at the macroscopic level. Margin migration will not occur until a wound is fully granulated (depth fully eliminated) and epithelial

migration can proceed. Surface area can reduce at this early time frame but it is secondary to contraction which can be asymmetrical and difficult to measure as described in the policy. Furthermore, the 1 mm/wk does not take into account the initial size or depth of the wound.

As providers, clinicians and researchers, we are not aware of any clinical evidence that would support either the statement "with appropriate care, wound volume or surface dimension will demonstrate advancement of no less than 1mm/week" or that "with appropriate care, wound volume or surface dimension should decrease by at least 10 per cent per month" and do not believe that it is appropriate for a value to be arbitrarily established absent scientific evidence to support it.

There are a variety of factors that determine the rate of closure for patients. These factors vary based on, but not limited to, the type and size of the wound and presence of co-morbidities. As such, the Alliance believes that while there are specific measureable changes that can be utilized for wound healing, specific values should not be utilized – especially when they are arbitrarily established.

Recommendation: The Alliance reiterates our objections to the use of value to determine wound healing. As such, the Alliance recommends that:

1. Novitas remove any references to value within the indications portion of the policy and delete "1 mm/wk and 10 per cent per month".
2. The sentence be modified to read, "Debridements of the wound(s) if indicated must be performed judiciously and at appropriate intervals. It is expected that, with appropriate care, and no extenuating medical or surgical complications or setbacks, wound volume or surface dimension should decrease overtime. It is also expected the wound care treatment plan is modified in the event that appropriate healing is not achieved".

If Novitas includes decides not to include the Alliance's recommended language, we request that Novitas provide the standards of care and the studies that were utilized for the basis of the arbitrary value utilized in this policy.

DISPOSABLE NPWT

Language in the Policy: Disposable NPWT devices must be a system and contain all three components (suction pump, exudate collection chamber and dressing sets). In these systems, exudate is completely removed from the wound site to the collection chamber. The device must also have safety monitors and alarms in place for patient use.

Concerns: The Alliance is pleased that Novitas has recognized that NPWT technologies have advanced and has decided to cover disposable NPWT. However, there are concerns with language contained in the policy which we request to be resolved prior to this policy becoming finalized.

There are several different types of disposable NPWT; each provides the ability to ensure the exudate has been removed and isolated from the wound bed. All of these systems have an exudate management

collection system - Some systems may extract the exudate to a separate canister, some do not have canisters at all; but all of the disposable NPWT products that are currently in the marketplace collect and isolate exudate in one fashion or another – depending on the manufacturer. The Alliance believes that all the disposable NPWT products should be covered under this policy as long as the exudate is being removed from the wound.

As a point of clarification- it appears that the disposable NPWT covered under this policy are included under the G codes issued by CMS under the OPPS. The current descriptor for the G codes is for mechanical NPWT. However, since the development of the new G codes, CMS has already acknowledged that all types of disposable NPWT will be covered under the G codes. To make the policy clear, adding a clarifying statement in the policy that G codes apply to both mechanical and electrical devices would be helpful. The Alliance would like clarification on this point as many of our members utilize not only mechanical but also electrical disposable NPWT and would like to ensure that these products will be covered under this policy as well.

Recommendations: The Alliance would like to recommend that Novitas:

1. Edit the language "Disposable NPWT devices must be a system and contain all three components (suction pump, exudate collection chamber and dressing sets)" to read "Disposable NPWT devices must be a system and contain a suction pump, and a type of exudate management collection system – such as a canister, collection device or any other type of exudate management collection system - and /or dressings".
2. Cover all disposable NPWT systems such that they meet the requirements outlined in the coding and coverage criteria.
3. Add a clarifying statement in the policy that G codes apply to both mechanical and electric disposable NPWT.

LOW FREQUENCY, NON CONTACT, NON THERMAL ULTRASOUND

Language in the Policy: Low-frequency, non-contact, non-thermal ultrasound (MIST Therapy) will be considered "reasonable and necessary" wound therapy and therefore eligible for coverage by Medicare when provided as wound therapy for any of the following clinical conditions:

1. Wounds, burns and ulcers meeting Medicare coverage for debridement but which are too painful for sharp or excisional debridement.
2. Wounds, burns and ulcers meeting Medicare coverage for debridement but with documented contraindications to sharp or excisional debridement.
3. Wounds, burns and ulcers meeting Medicare coverage for debridement but with documented evidence of no signs of improvement after 30 days of standard wound care.

Concerns: Novitas incorrectly describes non-contact ultrasound. Non-contact ultrasound is not a debriding agent; it stimulates cell activity and destroys bacteria. Yet, in the conditions for coverage,

Novitas describes criteria as if these products are agents for debridement. Contact ultrasound systems are debriding tools NOT non-contact ultrasound. Therefore, the Alliance would like to request that Novitas change the conditions for coverage of non-contact ultrasound so that there is no reference to debridement – since it is incorrect to do so.

While MIST Therapy can be regarded as providing low-frequency, non-contact, non-thermal ultrasound, recently, an AMA CPT Editorial panel has already acknowledged that the new CPT code 97610 remains appropriate for other ultrasonic devices when used to provide the same therapy under that code. To make the policy clear, removing the citation for a specific device would be helpful to clarifying the policy and needlessly necessitating its revision. The Alliance would like clarification on this point as many of our members utilize not only MIST Therapy but also other Ultrasound Wound Therapy (UWT) devices and would like to ensure that these products will be covered under this policy as well.

Recommendations: The Alliance recommends that Novitas modify the language to read as follows:

1. Edit the language from "Low-frequency, non-contact, non-thermal ultrasound (MIST Therapy) will be considered "reasonable and necessary" wound therapy and therefore eligible for coverage by Medicare when provided as wound therapy for any of the following clinical conditions:" to read as follows "Low-frequency, non-contact, non-thermal ultrasound will be considered "reasonable and necessary" wound therapy and therefore eligible for coverage by Medicare when provided as wound therapy for any of the following clinical conditions:"

2. Edit the language for clinical condition (1) from "Wounds, burns and ulcers meeting Medicare coverage for debridement but which are too painful for sharp or excisional debridement." to read as follows: "1. Performing low frequency, non-contact, non-thermal ultrasound, including topical application(s) on wounds, burns, and ulcers meeting Medicare coverage for stimulating cell activity and destroying bacteria, wound assessment, and instruction(s) for ongoing care, as prescribed per day."

3. Remove clinical condition (2).

4. Edit the language for clinical condition (3) from "3. Wounds, burns and ulcers meeting Medicare coverage for debridement but with documented evidence of no signs of improvement after 30 days of standard wound care." to read as follows: "2. Performing low frequency, non-contact, non-thermal ultrasound, including topical application(s) on wounds, burns, and ulcers with documented evidence of no signs of improvement after 30 days of standard wound care meeting Medicare coverage for stimulating cell activity and destroying bacteria, wound assessment, and instruction(s) for ongoing care, as prescribed per day."

BIOENGINEERED SKIN SUBSTITUTES

The Alliance applauds the efforts of Novitas and the language that is contained in this section of the draft LCD. Based on the language, all the CTPs that are listed would be covered – assuming

they are medically necessary and reasonable, documentation is contained in the patient's medical records and the product is provided in accordance with the package label. The Alliance agrees with this approach. We do however, have some specific comments in which we hope that Novitas will address prior to this draft becoming final.

The Term "Bioengineered Skin Substitute" is Clinically Inaccurate and Should be Replaced with the More Inclusive Descriptor "Cellular and/or Tissue Based Products for Wounds (CTPs)".

The Alliance is concerned with Novitas using the term "bioengineered 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. Instead, the Alliance recommends that Novitas adopt the term "Cellular and/or tissue based products for wounds (CTPs)" which does accurately describe and is broad and inclusive of both current and future technology. The Alliance recently voted positively on adoption of this term and, as mentioned above, we will be using the acronym "CTPs" when referring to Cellular and/or tissue based products for wounds in this document instead of 'bioengineered skin substitutes."

The Alliance submits that the term "skin substitute" is misleading and inaccurate to describe the products that are the subject of this LCD for the following reasons:

- This term is not used by either regulatory agency--FDA in its classification of these biologic products nor by CMS in its coding descriptors.
- 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 cells and/or tissue for homologous use not devices). CMS thus changed the descriptors and eliminated the term "skin substitutes" from all of its Q codes for these items.
- In addition, the Agency for Healthcare Research and Quality (AHRQ), in its 2012 final draft technology assessment on skin substitutes inferred that these products were not "skin substitutes," when the Agency stated:

> *"A true "skin substitute" would act like an autologous skin graft in adhering to the wound bed while providing the physiological and mechanical functions of normal skin. The skin substitutes included in this report contain various combinations of cellular and acellular components intended to stimulate the host to regenerate lost tissue and replace the wound with functional skin. Presumably, successful healing during management with these products would also require*

maintenance of a moist wound environment and other procedures thought to promote healing."

In 2012, the Alliance embarked on a yearlong effort to determine an appropriate term. In order to achieve a fair and inclusive process for determining this new term, a workgroup of scientists, clinical organizations, and business entities was created from the Alliance to address this issue. Such diverse multidisciplinary clinical specialties societies as the American Podiatric Medical Association, Society of Vascular Medicine, American Society of General Surgeons, Association for the Advancement of Wound Care, American Professional Wound Care Association, American Board of Wound Management and the American Physical Therapy Association participated in this process.

The following were the criteria used to select the new term:

- be based on science
- be inclusive of all products in marketplace today with eye towards what is in the "pipeline"
- be neutral in regards to FDA--- nothing that would be offensive and not allow manufacturers to get their products approved in the future if needed
- ensure that all products are eligible for Medicare coverage as drugs and biologicals consistent with their USP monographs
- easily understood by clinicians
- easily linked to the existing CPT codes for the application of the products

The Alliance reviewed over 18 different names during this process and selected the term "Cellular and/or tissue based products for wounds (CTPs)" since it met the criteria listed above.

As such, the Alliance recommends that Novitas not utilize the term "bioengineered skin substitute" in its policy and instead use the term "cellular and/or tissue based wound care products for wounds (CTPs)".

INDICATIONS

Language in the policy: any bioengineered skin substitute may be considered reasonable and necessary if it is provided in accordance with the material's Food and Drug Administration (FDA) approved package label with respect to application requirements, frequency, etc.

Concerns: The Alliance is concerned that Novitas is requiring information that does not exist for some of these products in order for the coverage criteria to be met.

CTPs have several FDA pathways to enter the market thus different package labeling and package inserts**:**

- PMA and 510K products are approved with specific indications for use and have FDA approved package labels.
- Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) have another FDA pathway and have package instructions for use.

The authority for the HCT/P framework is the Federal Food Drug & Cosmetic Act, which requires premarket clearance or approval for certain products, Sections 351 and 361 of the Public Health Service Act (PHS Act), and 21 CFR 1271, which FDA promulgated to effectuate the requirements for tissue products. The FDA regulatory framework for HCT/Ps has been in place and routinely enforced for 14 years.

A product eligible for regulation as a 361 HCT/P solely under Part 1271 is not subject to premarket clearance or approval. To be a 361 HCT/P, the product must meet all four of the following criteria:

1. It is minimally manipulated.
2. It is intended for homologous use as determined by labeling and advertising.
3. Its manufacture does not involve combination with another article, except for water, crystalloids, or a sterilizing, reserving, or storage agent.
4. It does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function.

The overarching policy for this two-tiered framework is that, in developing the regulatory framework for HCT/P products, FDA considered the long history of clinical use of tissue products and the existing body of clinical evidence for human tissue. Based on this body of evidence, the FDA determined that when they are minimally manipulated, intended for a homologous use, not combined with other articles, and do not have a systemic effect, tissue products are ***safe*** and may be marketed and used without any FDA pre-market review, clearance, or approval – thus they do not have any FDA approved package instructions. However, if the product is more than minimally manipulated there is a higher risk and therefore PMA or 510K approval is required – thus these products do have FDA approved package instructions.

Therefore, HCT/Ps do not have any FDA approved package instructions; instead they have instructions for use. Those products that are more than minimally manipulated have a higher risk and thus, they are required to seek PMA or 510K approval. These products do have FDA approved package instructions.

Recommendation: The Alliance recommends that Novitas edit the draft policy language which reads, "any bioengineered skin substitute may be considered reasonable and necessary if it is provided in accordance with the material's Food and Drug Administration (FDA) approved package label with respect to application requirements, frequency, etc." and instead utilize the following language, "any CTP may be considered reasonable and necessary if it is provided in accordance with the materials packaging instructions with respect to application requirements, frequency, etc."

OTHER INFORMATION – DOCUMENTATION REQUIREMENTS

Language in the Policy: The record must document that wound treatments with bioengineered skin substitutes are accompanied by appropriate adjunctive wound care measures such as dressing changes during the healing period, appropriate compressive dressings, appropriate off-loading, etc.

Recommendation: The Alliance would like to recommend that instead of using the language "appropriate off-loading" in this policy, Novitas use the language "proven off-loading" in its place.

HCPCS CODE

Finally, The Alliance noticed two errors with the HCPCS codes listed in this draft policy:

1. Novitas incorrectly included Endoform Dermal Template in this policy. The "C" code referred to in the policy (C9367) was terminated effective 12/31/2012 per the 2013 HCPCS corrections at www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2013-HCPCS-Corrections.html<http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2013-HCPCS-Corrections.html> and Endoform Dermal Template is now coded with A codes. The Coalition recommends removing Endoform from the list of HCPCS codes covered under this policy.

2. The description for Q4123 is not complete. The descriptor should read as follows: Q4123 Alloskin RT. Q4115 is for standard Alloskin. **The Alliance therefore recommends changing the descriptor for Q4123 to Alloskin RT.**

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On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director