ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

July 18, 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 LCD, "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.

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

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". 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.

In regards to coverage of CTPs, the Alliance recognizes the challenges and difficulties that the A/B MAC contractors such as Novitas are facing in managing the LCD development process with so many of these products entering the marketplace. We know that Novitas has attempted to establish a fair, balanced and accurate coverage policy and has taken into account the various forms of clinical evidence on which to establish coverage for these important CTPs.

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 standard of care that supports either the statement – "that the wound should decrease by at least 10 per cent 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 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.

RECOMMENDATIONS: The Alliance would like to reiterate our objections to the use of value to determine wound healing. As such, the Alliance recommends that:

- Novitas remove any references to value within the indications portion of the policy and delete "1 mm/wk and 10 per cent per month".
- 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 should decide to include a value, then the Alliance would like to recommend the following language, "It is expected that, with the appropriate care, and no extenuating medical or surgical complications or setbacks, wound volume or surface dimension should generally decrease by 10 percent per month".

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

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. Furthermore, the policy states, "Based on the expectation that the wounds are low exudating, the need for drainage collection canister would not be expected." Since disposable NPWT is provided as an alternative to DME based NPWT in patients with wounds of short duration, no more than 2 applications of a disposable device would be expected. Otherwise the patient is a candidate for DME based NPWT."

Concerns: The Alliance is pleased that Novitas has recognized that technologies have advanced and has decided to cover disposable NPWT. We agree that disposable NPWT should be used for a short duration and that it should be used for low exudating wounds. However, there are concerns with other language contained in the policy which we request to be resolved prior to this policy becoming finalized.

1. 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 disposable NPWT systems have an exudate collection management system which collect and isolate exudates. However, each "exudate collection management system" is referenced differently depending on the manufacturer. The Alliance believes that all the disposable NPWT products should be covered under this policy as long as the device removes exudate from the wound and is indicated for low exudating wounds.

2. Furthermore, the Alliance disagrees with the number of applications in the draft LCD. To limit the applications to no more than 2 is too short of a time to determine the effectiveness of any system on wounds such as those which require short term use of NPWT in order to increase wound bed granulation thus achieving delayed primary healing or post-graft placements for diabetic foot ulcers so as to increase graft take.

3. The Alliance is seeking clarification as to whether Novitas believes that the expectation is that the disposable NPWT device will be used for short term consideration and only two devices will be allowed in a 30 day period. The indications, limitations and life span of each disposable NPWT system are different and should be taken into consideration for this coverage policy.

4. Finally – it appears that the disposable NPWT covered under this policy is required to utilize 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 Code. As stated below in our recommendations, we ask that Novitas add a clarifying statement in the policy that G Codes apply to both mechanical and electric. This point should be clarified as many of our members manufacture 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 recommends that Novitas:

1. Remove the language in the policy which states, "Based on the expectation that the wounds are low exudating, the need for a drainage collection canister would not be expected" as all of the disposable NPWT systems have an exudate management collection system (e.g., canister, and/or collection chamber and/or dressing system) which is used to collect and isolate the exudate.
2. 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: "A disposable NPWT device must be a system and contain a suction pump, and any type exudate management collection system (e.g., canister, and/or collection chamber and/or dressing system)"
3. Cover all disposable NPWT systems such that they meet the requirements outlined in the coding and coverage criteria.
4. Delete the language referring to no more than 2 applications. We also recommend that Novitas limit the number of applications based on the manufacturers' indications for use for each individual product.
5. Add a clarifying statement in the policy that G Codes apply to both mechanical and electric disposable NPWT.

BIOENGINEERED SKIN SUBSTITUTES

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.

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 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.

- 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 "skin substitute" in its policy and use the term "cellular and/or tissue based wound care products for wounds (CTPs)".

Provision of Specific Criteria for Coverage is Necessary

Novitas has stated that in order to consider a CTP for coverage, a supporting level of medical evidence including at least one published (or accepted for journal publication) peer-reviewed randomized controlled

trial (RCT), is required. Novitas further states that "An RCT may be performed on a contingency basis at the discretion of the local contractor".

The Alliance is concerned and disagrees with the statement, "An RCT may be performed on a contingency basis at the discretion of the local contractor". We request clarification of this statement since it does not seem to be very transparent as Novitas is not specifying what is being required for coverage. It is unclear when some devices will be required to comply with the RCT data stated in this policy and when others will be required to have an RCT performed on a contingency basis. Manufacturers need to have clear direction on what is required for coverage and this policy does not provide that guidance.

Evidence can be established for coverage not only through RCTs but also through a combination of retrospective clinical studies (relevant since the populations of patients that demonstrate a need for the products in question would be *eliminated* in many and most RCTs), 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 CTPs 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.

Recommendations: The Alliance recommends that Novitas:

1. Delete the following language from the LCD prior to it becoming final – "An RCT may be performed on a contingency basis at the discretion of the local contractor"
2. Allow for other types of clinical trials to be accepted as evidence when it considers covering a new CTP product.
3. Must specifically detail what is required for coverage, in order to be more transparent. We would recommend that Novitas follow examples of A/B MAC contractors who have provided this information in their LCDs such as CGS, NGS and NHIC.

Indications and Limitations for Coverage of Products

1. **Language in the policy:** In order for the products identified under this section of the policy to be covered – it appears that they need to be used solely on venous stasis ulcers and neuropathic diabetic foot ulcers.

   Concerns: The Alliance questions the limitation in the policy for only "neuropathic" diabetic foot ulcers in some therapies and a broader indication of diabetic foot ulcers in others. The policy implies that coverage for these products- if they are used to treat a diabetic foot ulcer - would only be available for a beneficiary with a neuropathic diabetic foot ulcer. The specification of neuropathic diabetic foot ulcers will eliminate many other causes of foot ulceration in the diabetic patients and deny coverage and appropriate care for a large segment of Medicare population.

Furthermore, many products that are identified in this draft policy have been covered based on medical necessity for all FDA cleared indications for use. However, this draft policy appears to deny coverage for all of the cleared indications except for neuropathic diabetic foot ulcers and venous stasis ulcers. The Alliance believes that the products identified in this policy should be covered for all of the clear indications for use.

Recommendations: The Alliance recommends to be consistent with all other A/B MAC medical policies that Novitas eliminate the word neuropathic. The language should simply state diabetic foot ulcers. The Alliance also recommends that Novitas follow the FDA cleared indications for use for all the products identified in this draft policy and make the necessary changes in the policy before it becomes final.

2. **Language in the Policy**: Retreatment of an ulcer following an unsuccessful course of treatment is not covered. Retreatment of a successfully treated healed ulcer is not covered.

   Concerns: An additional issue within this section pertains to the language that retreatment of a successfully healed ulcer is not covered nor is retreatment of an ulcer following an unsuccessful course of treatment. This is hugely problematic as patients can - down the road - develop another ulcer in the same location, can have further breakdown or another type of product can be placed on the wound after an unsuccessful course of treatment of one type of product.

   Recommendations: The Alliance does not agree with the language as drafted in this policy as it is not appropriate to eliminate coverage for a Medicare beneficiary if they have further breakdown after a successful treatment of a wound or if a particular product was tried unsuccessfully on a patient and the clinician determines that another product may be used to help heal the wound. We therefore recommend that this language be eliminated from the policy as it is not clinically sound.

3. **Language in the Policy:** Only apply skin substitutes to wounds with adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (presence of acceptable peripheral pulses and or ankle brachial index (ABI) of no less than 0.65).

   Concerns: The Alliance maintains that the language which requests the "presence of acceptable peripheral pulses" is not only vague, but there is no clinical evidence which supports it. As such, the Alliance would like to request that Novitas provide the clinical findings which support the presence of acceptable peripheral pulse.

   Recommendations: The Alliance recommends that Novitas eliminate "presence of acceptable peripheral pulses" from the draft LCD before it becomes final as it is vague and there is no clinical evidence which supports it.

OTHER INFORMATION – DOCUMENTATION REQUIREMENTS

1. 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.

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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.

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Executive Director